

An Evaluation Of Knowledge, Attitude, And Practice Of Adverse Drug Reaction Reporting Among Prescribers At Tertiary Care Hospitals

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INTRODUCTION:

Adverse drug reaction (ADR) is defined by the world health organization (WHO) as a harmful and unintended response to a drug that occurs at doses that are typically used in humans for the treatment of the disease, diagnosis, prevention, or the modification of physiological function [1]. It is a global problem that has a significant concern among the community and health care system [2, 3]. ADRs are commonly encountered in daily practice; however, many are preventable [4]. The prevalence of ADR is increasing; and was reported to be 12%, 11.5%, 12.9%, and 16.6% in Sweden [5], Norway [6], and New Zealand [7], respectively.

ADRs could lead to considerable morbidity and mortality within health care providing systems. They are associated with 6.5% hospital admissions in the U.K. healthcare system and are responsible for 5,600 hospital admissions annually [8]. ADRs were responsible for 0.7% hospital admission in India, and a total of 3.7% of hospitalized patients experienced ADRs, of which 1.3% were fatal [9]. ADRs are responsible for 5% in the US [10]. A higher rate of hospital admissions, reaching 24.5% emergency department admissions in Saudi Arabia, is attributed to ADRs [11]. However, around 70% reported ADRs could be prevented with proper reporting and management, especially when it is recognized that 7% of the admitted cases were attributed¹ to drug-drug interactions [12, 13].

ADR reporting or pharmacovigilance involves principles and practices for detecting, evaluating, interpreting, and preventing any common problem related to the use of a drug [14]. The WHO defined pharmacovigilance as the activities and science relating to detecting, assessing, understanding, and preventing ADRs or any other problem related to drugs [15]. The main goal for documenting ADRs is patient safety [16] by preventing future complaints, and ADRs experienced by the patients. New ADRs are often discovered when the drugs are used in different populations and have a more considerable duration than studied and reported in the clinical trials [17, 18]. Several surveillance systems were adopted to predict the suspected ADRs, such as record linkage schemes, voluntary reporting systems, and electronic local or international databases [19]. The advantages of a voluntary reporting system include being inexpensive, easy to operate, and encompassing all drugs and patient populations [4]. However, the voluntary reporting system has a limitation of having a narrow spectrum of reports, where less than 10% of severe ADRs were detected [20]. The ADR reporting by physicians was found

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to be 5-34% only as reported from 15 studies from the the University had never reported, submitted, or identified any ADR [22].

In Saudi Arabia, in March 2009, the National Pharmacovigilance Center was established by the Saudi Food and Drug Authority [23]. The center collects, evaluates, and communicates information from other members regarding the drugs' harm, risks, benefits, and effectiveness. The spontaneous (voluntary) reporting system is the primary way to gather information about ADRs in any setting, including hospitals [24]. Healthcare providers have an essential role in detecting and reporting ADRs [25]. All the health care providers should report ADRs as a part of their professional responsibility [26], so it is essential to increase their awareness about ADR reporting as this will help them improve the ADR reporting [27]. The effectiveness of a post-marketing surveillance program is dependent on the active participation of health professionals [26]. Therefore, it is necessary to identify healthcare providers' knowledge about these surveillance systems and programs, their attitude toward them, and their level of practice [28].

The knowledge and barriers to reporting ADR by physicians in tertiary care hospitals were investigated in Saudi Arabia. Among 600 physicians who participated, 85.4% correctly defined ADR; however, most physicians (75%) were unaware of spontaneous reporting ADR in Saudi Arabia. Moreover, 72.9% reported that they didn't report any ADR. Less than one-half of physicians reported the barrier of reporting ADR as they were unaware of the online reporting ADR [16].

A study that included seven hospitals in the Holy city of Makkah revealed that the health professionals were aware of ADR and had a positive attitude to report ADR. However, there were several barriers to reporting ADRs, including insufficient clinical knowledge, fear to report ADR, non-availability of forms, and lack of training [29]. Another Saudi study performed at KFHU on health professionals showed a lack of awareness and knowledge regarding ADRs reporting [24]. A study performed at three general hospitals in Jeddah demonstrated that physicians need ADR training programs to enhance their knowledge, attitude, and practice of ADRs and reporting [30].

A study was carried out in the teaching hospital in Sikkim, India, on health professionals reported that the respondents had average knowledge and positive attitude toward ADR reporting; however, ADR reporting practice was poor among participants as most of them (79%) weren't aware of the presence of ADR monitoring center, and a higher percentage (87%) reported they didn't send filled ADR forms to the monitoring center [31, 32]. Another study from India was carried out at a tertiary care hospital and conducted among prescribers revealed that the prescribers were aware of ADRs and the importance of reporting ADRs. However, the prescribers lacked knowledge about the reporting system, and as a result, there was under-reporting practice among them. In addition, the respondents lack information about where and how to report ADRs and lack access to reporting forms [4].

In Malaysia, a study conducted on health care professionals at primary outpatient care showed inadequate knowledge among respondents, and there was an unsatisfied attitude and practice among them. This shows the failure to report ADR even if the ADR is identified [33]. In Nepal, a study was enrolled on doctors, and nurses found an excellent knowledge among doctors and nurses regarding reporting of ADRs. However, there was a gap in training and experience on the ADR reporting system [34]. Therefore, this study aimed to evaluate prescribers' knowledge, attitude, and practice (KAP) levels at tertiary care hospitals.

MATERIALS AND METHODS:

A cross-sectional study was conducted at tertiary care hospitals (Jazan Armed Forces Hospital, Jazan, Saudi Arabia) among prescribers between May to October 2021. The study used a questionnaire to investigate the level of KAP among prescribers. In addition, the demographics, level of knowledge, attitude, and practice of prescribers were investigated.

Prescribers working at tertiary care hospitals were included, and prescribers not working at tertiary care hospitals were excluded.

Data were collected using a pre-designed questionnaire. The questionnaire involved questions to investigate the demographics of the prescribers, such as age, gender, education level, marital status, and experience years. The questionnaire also involved questions to investigate the knowledge, attitude, and practice.

The data were collected from all respondents by retrieving the questionnaire distributed between them and was saved in an excel sheet then transferred and analyzed by the SPSS program. Categorical variables were represented using numbers and percents, whereas numerical variables were represented using mean \pm SD. According to the type of the variable, correlations were also performed using a T-test or Chi-square. P-value was considered significant at ≤ 0.05 .

RESULTS:

Of 152 prescribers included in the current study, 77(50.7%) were males, and 75(49.3%) were females. The age group included those aged 31-35 years old, representing the most significant proportion of participants 62(40.8%) (Table 1).

Table 1: Description of study variables

Variables	Description(n=152)
Sex	
Male	77 (50.7)
Female	75 (49.3)
Age	
< 30	43 (28.3)
31-35	62 (40.8)
> 35	47 (30.9)

The level of KAP among prescribers was assessed in this study through 14 questions. Regarding knowledge, there were 67(44.1%) who only reported awareness about drugs that have been banned due to ADRs. Regarding the attitude of prescribers regarding ADRs, there were 94(61.8%) and 52(31.2%) who thought that reporting ADRs is vital, respectively. Therefore, the practice of reporting ADRs was reported by 81(53.3%) (Table 2).

Table2: Questions and answers of prescribers about the KAP questions

Questions and answers	N(%)
are you aware of any drug that has been banned due to ADRs?	
Yes	67 (44.1)
No	85 (55.9)
how important do you think it is to report ADRs?	
very important	94 (61.8)
Important	52 (34.2)
not very important	6 (3.9)
why is it important to report ADRs?	
to identify and detect new ADRs	61 (40.1)
to share information about ADRs with colleagues	55 (36.2)
to improve patients safety	110 (72.4)
to identify relatively safe drug	35 (23)
to measure the incidence of ADRs	33 (21.7)
have you ever reported an ADRs?	
Yes	81 (53.3)
No	71 (46.7)
where?	
an ADR reporting center	59 (72.8)
the concerned pharmaceutical company	16 (19.8)
Others	6 (7.4)
what factors do you think are important while deciding to report an ADR?	
unusual reaction	94 (61.8)
involvement of new drug	92 (60.5)
confidence in the diagnosis of an ADR	49 (32.2)
what are the factors that discourage you from reporting ADRs?	
did not know how to report	32 (21.1)
not knowing where to report	41 (27)
did not think it to be important	13 (8.6)
managing patients was more important than reporting ADRs	7 (4.6)
lack of access to reporting ADRs	19 (12.5)
patients confidentiality issue	0 (0)
legal issue	6 (3.9)
concerns about professional liability	1 (0.7)
Other	33 (21.7)
in your view, which ADRs should be reported	
none	12 (7.9)
all ADRs	71 (46.7)
all serious ADRs	27 (17.8)
ADRs to new drug	10 (6.6)
unknown ADRs to an old drug	3 (2)
ADRs to vaccine	0 (0)
Other	29 (19.1)
are you aware of any drug reporting center where you can report ADRs?	

Yes	99 (65.1)
No	53 (34.9)
have you ever shared information about ADRs with anyone?	
Yes	105 (69.1)

No	47 (30.9)
from which source do you gather information about ADRs to new drug	
textbooks	65 (42.8)
journals	45 (29.6)
drug advertisement	21 (13.8)
medical representative	59 (38.8)
brochures	14 (9.2)
conferences	14 (9.2)
internet	70 (46.1)
do you have free access to ADR reporting access?	
Yes	82 (53.9)
No	70 (46.1)
which method would you prefer to send ADR information to an ADR reportingcenter?	
direct contact	34 (22.4)
telephone	13 (8.6)
post	0 (0)
email	73 (48)
Other	32 (21.1)
in your opinion, which of these are qualified to report ADRs?	
medical representative	40 (26.3)
nurses	12 (7.9)
pharmacists	66 (43.4)
dentists	0 (0)
physiotherapies	0 (0)
health workers	34 (22.4)
patients /consumer	0 (0)

The overall level of KAP was estimated based on the 14 questions, and the overall KAP showed that only 50(32.9%) had a high level of KAP, whereas 102(67.1%) had a low level (Figure1).

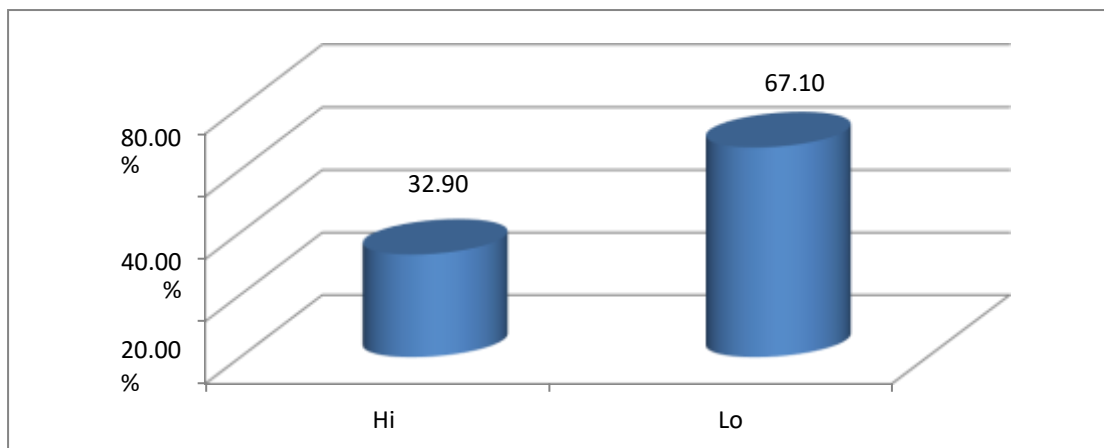


Figure 1: The overall KAP among prescribers.

There were significant associations between KAP level and sex of prescribers (P=0.0001), reporting ADRs(P=0.011), and free access to the ADR reporting system (P=0.016) (Table 3).

Table 3: Factors affecting KAP level

	KAP Level		P value
	High (n=50)	Low (n=102)	
sex			
Male	37 (74)	40 (39.2)	0.000
Female	13 (26)	62 (60.8)	
Age			
< 30	18 (36)	25 (24.5)	0.075
31-35	14 (28)	48 (47.1)	
> 35	18 (36)	29 (28.4)	
Are you aware of any drug that has been banned due to ADRs?			
Yes	19 (38)	48 (47.1)	0.291
No	31 (62)	54 (52.9)	
Have you ever reported an ADRs?			
Yes	34 (68)	47 (46.1)	0.011
No	16 (32)	55 (53.9)	
Are you aware of any drug reporting center where you can report ADRs?			
Yes	35 (70)	64 (62.7)	0.378
No	15 (30)	38 (37.3)	

Have you ever shared information about ADRs with anyone?			
Yes	39 (78)	66 (64.7)	0.096
No	11 (22)	36 (35.3)	
Do you have free access to ADR reporting access?			
Yes	20 (40)	62 (60.8)	0.016
No	30 (60)	40 (39.2)	

Discussion

In the current study, less than one-half of prescribers reported having awareness about drugs banned due to ADRs. However, most prescribers reported that reporting ADRs was critical, and the main reason was to improve the safety of the patients. In a previous Saudi study, the large majority of participants (92.62%) reported that the ADRs reporting system was critical [21], and this percentage was almost close to the current study.

A study from Jeddah reported that more than 60% physicians didn't fully understand ADR's reporting perspective. This low awareness could be attributed to the lack of training and educational programs, where 72% physicians reported that they were never exposed to ADRs training programs [30]. In the current study previous trainings were not investigated.

Similar to the current findings, a study from India conducted on prescribers revealed that most respondents considered that reporting ADRs was necessary. The main reasons were the safety of patients and identifying new ADRs [4].

Practicing reporting ADRs was reported by only 53.3% of the current participants, mainly in the ADR reporting center. The major obstacles that lowered the attitude of prescribers for reporting ADRs included being unaware of where and how to report the ADRs. Also, 53.9% reported having free access to the ADR reporting system. In a previous Saudi study conducted on physicians, it was found that 72.9% hadn't reported ADRs in the previous year, and the leading cause of not reporting ADRs was unaware of online reporting of ADR system (40%) [16].

Another Saudi study conducted on seven hospitals in Makkah reported a positive attitude among health professionals regarding reporting ADRs; however, there were several barriers such as no availability of forms, lack of training, fear to report ADRs, and insufficient clinical knowledge [29].

A lower practice was reported in a previous Saudi study conducted on physicians and dentists; the study revealed that only 35.68% reported ADRs [21].

In Jeddah, one study demonstrated that most respondents (more than 90%) showed a positive attitude toward ADRs and ADRs monitoring and reporting systems. A higher proportion compared to the current study reported that they come across ADRs in practice, but only 21.7% reported these reactions, which were [30] lower than the current findings.

Only 15% prescribers from India reported ADRs previously, and this proportion was lower compared to the present study. The obstacles for reporting ADRs included that participants didn't know where (70%), and how (68%) to report ADRs, and the lack of access to reporting

forms (49.2%) [4]. The previous obstacles were the same reported by the current prescribers.

The overall level of KAP among prescribers was low, where 67.1% had low KAP; the level of KAP considerably was influenced by sex, previous reporting of ADRs, and free access to ADR. Males and those who reported before ADRs were more likely to have higher KAP, whereas those who have free access to the ADR reporting system were more predisposed to have lower KAP. This might be attributed to that most of those who had free access doesn't know where or how to report ADRs.

In a tertiary hospital in Saudi Arabia, a study that included 600 physicians showed that physicians were adequately aware of ADRs [16]. A systematic review from Saudi Arabia included 27 studies published between 2010 to 2015; it was found that healthcare professionals had poor knowledge and practiced toward reporting of ADRs; however, they had a positive attitude [26].

CONCLUSION:

There was a low level of knowledge, attitude, and practice of reporting ADRs among prescribers at a tertiary hospital. Although the majority knew and reported that reporting ADRs is essential, there was low awareness regarding banned drugs due to ADRs. There was moderate practice as almost one-half stated that they previously reported ADRs. However, several obstacles were reported that prevented them from reporting ADRs, such as having no idea where and how to report ADRs and having no free access. So, establishing training programs and educational sessions about how to report ADRs, where to use ADRs, and informing participants about the list of banned drugs could improve prescribers' awareness, attitude, and practice.

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