


# Pharmacovigilance Perception and Knowledge Among Pharmacists and Interns in Saudi Arabia

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**Aim:** The aim of this study was to determine and compare the level of knowledge and perception of ADRs reporting and pharmacovigilance among interns and hospital pharmacists in different health-care settings in Saudi Arabia.

**Methods:** A cross-sectional study was conducted among pharmacists and pharmacy interns in different hospitals in Saudi Arabia. A total of 315 participants completed the self-administered and validated questionnaire during the period from August 2018 to March 2019.

**Results:** There was poor perception and knowledge of pharmacovigilance and ADRs reporting among pharmacists as well as intern pharmacists. However, pharmacists had better knowledge score compared to interns ( $P=0.043$ ). Most of the respondents believed that ADRs reporting is important. The majority of both interns and pharmacists stated that they did not receive adequate education about pharmacovigilance during their undergraduate or internship program.

**Conclusion:** There is a gap in knowledge and perception about pharmacovigilance among practicing pharmacists and new pharmacy graduates. Drug safety fundamentals and policies should be taught to undergraduate pharmacy students in Saudi Arabia.

**Keywords:** pharmacovigilance, adverse drugs effects, safety, pharmacists, Saudi Arabia

## Introduction

Pharmacovigilance is defined as the activity and science relating to collection, detection, monitoring, assessment, and prevention of adverse drug effects with pharmaceutical products.<sup>1</sup> The word “pharmacovigilance” is derived from the Greek word *pharmakon* (drug) and the Latin word *vigilare* (monitor or keep an eye on). Pharmacovigilance is a process of identifying the hazards related to pharmaceutical products.<sup>1</sup>

Pharmacovigilance plays an essential role in patient outcomes. Adverse drug reactions (ADRs) are defined by the World Health Organization (WHO) as “any noxious, unintended, and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or therapy.”<sup>2</sup> Data from a systematic review reported that ADRs were associated with 15% of admissions to hospitals and prolonged hospitalizations and they are considered as the fourth to sixth leading cause of mortality in the USA.<sup>3</sup> Patients who experienced any type of ADRs are hospitalized nearly 8–12 days longer than patients who did not experience ADRs.<sup>4</sup> Any medication usage can be associated with undesirable consequences.<sup>5</sup> The Center for Health Policy Research states that more than 50% of the approved medications in the USA are linked to some types of undesirable effects that were not discovered prior to the new medication approval process. Therefore, it is very important to improve the role of pharmacists in post-medication exposure and marketing surveillance.<sup>3</sup>

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A proper spontaneous reporting system for ADRs is a basic component for comprehensive post-marketing monitoring of drug-induced risks and the study of drug safety, where there are inadequate data due to the many limitations of premarketing clinical trials.<sup>6,7</sup> Although spontaneous reporting systems are simple to use and inexpensive, their potency is tightly linked to the actual reporting rate by health-care providers. Under-reporting is the main intrinsic and actual disadvantage.<sup>7</sup> Consequently, health-care providers' knowledge of pharmacovigilance and ADRs reporting systems could impact their attitude towards good patient care and safety.<sup>8</sup> Proper training for health-care providers, most importantly pharmacists, can improve the number of reporting ADRs. Previous studies showed that inadequate perception and awareness of ADRs reporting may eventually affect the reporting rate.<sup>1,8</sup>

Studies have been conducted inside and outside Saudi Arabia to examine the knowledge and perceptions of pharmacy students and staff about pharmacovigilance.<sup>10–14</sup> These studies have a significant role in guiding policymakers to prioritize their interventions, because they clearly demonstrate the need to increase awareness of the importance of pharmacovigilance and reporting adverse effects. Pharmacists and interns must understand their pivotal role in pharmacovigilance and the surveillance of the safe use of medicines. There has been no study focusing on the knowledge of pharmacy interns about pharmacovigilance and reporting side effects. Therefore, this study was aimed at assessing the knowledge and perception of pharmacovigilance among pharmacists and interns in Saudi Arabia. More specifically, this study attempted to answer two questions: Do the interns know better than pharmacists about pharmacovigilance? Do pharmacy colleges in Saudi Arabia need to offer specific classes in medication safety?

## Materials and Methods

This descriptive cross-sectional study was conducted among pharmacists and intern pharmacists in Saudi Arabia from August 2018 to March 2019 using a pretested and validated questionnaire which was administered through interviews or self-administered through online distribution. Participants were eligible if they graduated with a pharmacy degree or they are current pharmacy interns who deal with medications, and are willing to provide consent to participate in the study during the allocated data collection period. Pharmacy undergraduate students and those unwilling to provide consent for participation were excluded.

## Sample Size

Adequate sample size remains a major concern when conducting medical research, due to the unknown size of the population. Additionally, for online surveys, the researcher may need to enroll more participants in practice to account for potential missing/non-response error, because the researcher has no control over respondent response.<sup>15</sup> “Power study” is a very useful and frequently used tool to calculate sample size in the field of medical research. For the current paper the, “power study” method was performed using a Web-based sample size calculator using the necessary information retrieved from published articles in Saudi Arabia.<sup>16</sup> Moreover, sample size adjustment was done for missing/non-response using the following formula.

$$n_1 = n / (1 - d)$$

where  $n$  is required sample size as per formula,  $n_1$  is adjusted sample size and  $d$  is the potential missing or non-response rate. A minimum number of 230 samples can achieve more than 90% power when we consider only 1% margin of error and 30% missing/non-response error rate.

## Data Instrument Development and Quality Assurance

After an extensive literature review, an initial draft of a questionnaire was designed in the English language.<sup>8–13</sup> To ensure the study objectives are met, the structured questionnaire included information about attitude, knowledge, and practice on ADRs reporting and pharmacovigilance. From the initial set of 34 questions, the final questionnaire comprised a total of 28 questions and was divided into three domains: the first domain included 7 questions (with 2 of 9 questions excluded) concerned with demographic data such as degree program and gender; the second one included 10 questions (with 3 of 13 questions excluded) related to knowledge about ADRs reporting and pharmacovigilance; and the final domain consisted of 11 questions (with 1 of 12 questions excluded), designed to determine the perception of ADRs reporting. The questionnaire was piloted to ensure face validity and that all the necessary corrections had been addressed, and the piloted samples were excluded from the final analysis. To ensure data reliability, a number of adjustments were made during the design and data collection periods, including a clearly documented data collection process and a research procedure that was followed according to the data collection protocol; all of the data were gathered on one occasion to reduce the capture responses from participants as well as to reduce unintentional response bias.

## Content Validity and Reliability Analysis

The development of the questionnaire was carried out by a panel of seven experts including three clinical pharmacists (different departments, including pharmacy practice), two medical professionals (general practitioners), one social scientist, and one biostatistician. The content validity index (CVI) was calculated using the Yusoff<sup>16</sup> CVI calculation method for knowledge and perception. The I-CVI/Ave score was reported for a knowledge domain of 0.87 and for a perception domain of 0.91. According to Lynn,<sup>17</sup> the recommended score for CVI is 0.83 or more, so the obtained score was acceptable for the current study. In addition, reliability was tested by Cronbach's alpha and knowledge and perception values of 0.68 and 0.66 were obtained, respectively.

## Variable Measurement

Data were collected through an online survey (QuestionPro), and a high response rate was observed (71.05%: 481 out of 677). Knowledge and perception were two dependent variables. To assess knowledge, a 10-item (K1 to K10) questionnaire was utilized. To avoid response bias, an inverse item (K10) was included and "false" responses were considered good knowledge. Only the correct answers were considered as good knowledge for the first two items (K1 and K2). For the other items (K3 to K9), the responses "agree" and "strongly agree" were considered as good knowledge. Perception was assessed by an 11-item (P1 to P11) questionnaire. To assess good perception, the correct answer was reflected for the first item (P1) while "agree" and "strongly agree" were reflected for the rest of the items (P2 to P11). For data analysis, knowledge and perception were divided into two groups, good (knowledge/perception) and poor (knowledge/perception). Knowledge and perception scores were also calculated for further analysis. A higher score represents a higher level of knowledge and perception about pharmacovigilance. Information was also collected about some socio-demographic variables, including gender, age, work experience and place, educational degree and institute, and nationality.

## Data Management

Data cleaning is an important step before the final data analyzing procedure.<sup>18</sup> For the current study data were checked and cleaned for incomplete information and also

for extreme values using an informal technique.<sup>19,20</sup> As an online survey was involved, missing cases were inevitable; some were treated using a statistical method (the last observation carried forward method)<sup>21</sup> and some were excluded from the final analysis (Figure 1).

## Statistical Analysis

Statistical analyses were carried out using Statistical Package for Social Scientists (IBM SPSS version 23.0) and Excel software. Descriptive statistics and cross-tabulation were used to describe the study variables, and frequencies with their corresponding percentages are presented. An independent sample *t*-test was utilized to compare knowledge and perception score between interns and pharmacists. For statistical significance, any value of  $p < 0.05$  was considered an acceptable range of type-I error.

## Results

After excluding missing and abnormal cases from the data set, a total of 315 samples were analyzed for the current study. The majority of the participants (74.3%) were hospital pharmacists. More than half of the respondents were female (58.7%), while 41.3% were male. Regarding work experience, half (51.4%) of the respondents were interns (without having any previous experience), whereas 31.7% and 16.8% of respondents have work experience of up to 5 years and 6 or more years, respectively (Table 1).

When good knowledge about pharmacovigilance was compared between interns and pharmacists, it was found that among all items, pharmacists had better knowledge than interns. The maximum proportion of good knowledge (91.0% pharmacists' vs 86.4% interns) was reported for item-1 (pharmacovigilance is the practice of monitoring the effects of medical drugs after they have been licensed for use, especially in order to identify and evaluate previously unreported adverse reactions). However, the lowest proportion of good knowledge for item-10 (Type A ADRs are uncommon and unpredictable, depending on the known pharmacology of the drug; they are independent of dose and only affect few people) was reported (30.3% pharmacists vs 28.4 interns) (Table 2).

Table 3 represents the data of perception comparison. Results showed that among items 7 to 10, interns reported higher proportion of good perception about pharmacovigilance than pharmacists (item-7: 56.8% vs 50.0%, item-8: 74.1% vs 64.5%, item-9: 85.2% vs 81.6%, and item-10: 80.2% vs 78.6%, respectively), whereas for the rest of the items (item-1: 22.2% vs 32.1%, item-2: 29.6% vs 35.9%,

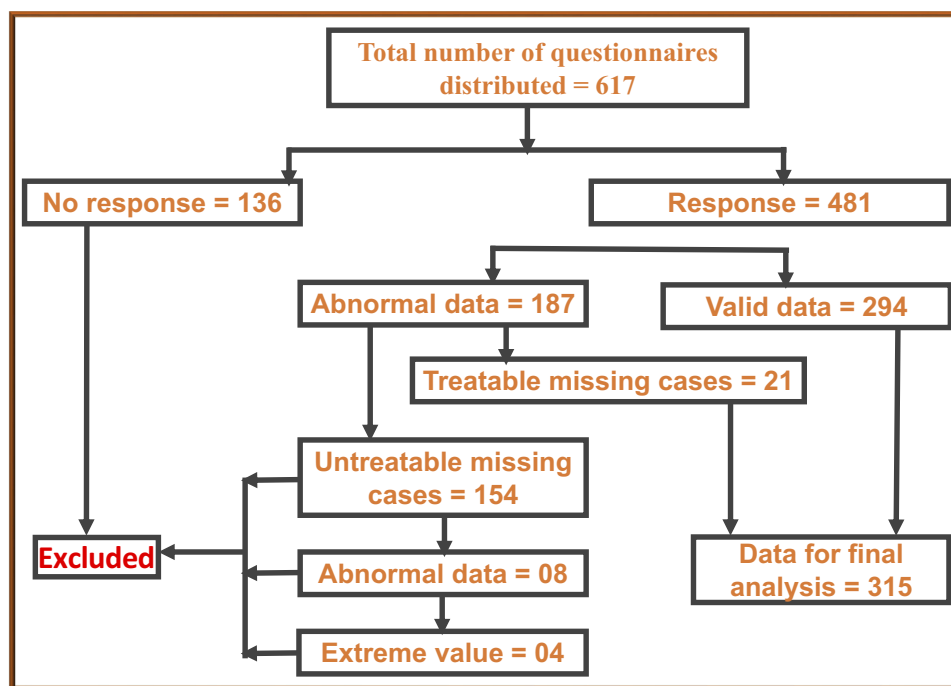


Figure 1 Data cleaning procedure.

item-3: 86.4% vs 87.2%, item-4: 30.9% vs 35.5%, item-5: 39.5% vs 49.6%, item-6: 38.3% vs 41.0% and item-11: 14.8% vs 16.2%) a lower proportion of good perception was demonstrated for interns than for pharmacists (Table 3).

Knowledge and perception scores were compared using an independent sample *t*-test. Results demonstrated that in regards to knowledge score, pharmacists have significantly higher knowledge score (MD=1.44;  $p<0.05$ ) than interns (mean score: pharmacist, 32.67 (SD: 5.34) vs intern 31.22 (SD: 6.01)). In terms of perception, although pharmacists showed a higher mean score than interns (mean score: 36.10 (SD: 6.03) vs 35.49 (SD: 5.72)), no statistically significant difference was found (Table 4).

## Discussion

The majority of the study population knew the correct definition of pharmacovigilance (PV). This might be because of the continuing education activities conducted by the top hospital management and supervised and monitored by the Saudi Food and Drug Authority (SFDA). The SFDA has drug safety coordinators in hospitals who aim to raise awareness and improve ADRs reporting. In addition, in the last few years the SFDA conducted annual conferences on drug safety. In this year (2019) the SFDA received the highest number of ADRs reports since its

establishment. Pharmacists must transfer their knowledge to the public to increase their awareness of ADR reporting. A study assessing PV knowledge among the public in Saudi Arabia found that only 15.7% of the public knows about the term “pharmacovigilance” and only 8.6% acknowledge awareness of the national PV center.<sup>22</sup>

In Saudi Arabia, ADRs reporting is regulated by the National Pharmacovigilance Center which is part of the SFDA. A study conducted in 2013 in the eastern region of Saudi Arabia found that 10% of community pharmacists were aware of the existence of the ADRs reporting system.<sup>23</sup> Another study performed in Riyadh in 2014 reported that only 22% of community pharmacists knew where and how ADRs reports are submitted.<sup>11</sup> A multicenter study conducted in three regions of Saudi Arabia reported that 67% of health-care professionals (physicians, pharmacists, nurses, and interns) were not aware of the existence of a National Pharmacovigilance Center.<sup>12</sup> There is a major improvement in the knowledge of pharmacists about the right regulatory body to which ADRs reports should be submitted. In the current study, more than three-quarters of the interns, as well as pharmacists, were aware of the fact that ADR reports should be submitted to the National Pharmacovigilance Center. However, technical details on the process of reporting ADRs were known to half of the interns and slightly more than half of the pharmacists. In addition,

**Table 1** Descriptive Statistics for Demographic Variables (n=315)

Gender	Frequency (n)	Percentage (%)
Male	130	41.3
Female	185	58.7
<b>Age (Year)</b>		
20–25	196	61.9
26–30	64	20.3
31 and above	56	17.8
<b>Education</b>		
Intern	81	25.7
Pharmacist	234	74.3
<b>Working experience</b>		
Intern	162	51.4
Up to 5 years	100	31.7
6 years and more	53	16.8
<b>Work place</b>		
MOH hospital	162	51.4
Other hospital	153	48.6
<b>Nationality</b>		
Saudi	299	94.9
Non-Saudi	16	5.1

more than half of the participants believed that they are not prepared with the knowledge and skills to report ADRs. Therefore, more efforts are needed from SFDA to clarify this issue to health-care professionals. Also, ADRs reporting forms should be simple to use, because this was one of the challenges and reasons for underreporting of ADRs in a qualitative study performed among health-care professionals in Riyadh.<sup>24</sup> More interns compared to pharmacists in this study believed that ADRs reporting should be mandatory. Interns are the future pharmacists and their positive perception is a good sign that much improvement in pharmacovigilance practice is anticipated in the coming decades. Similar to a recent study<sup>12</sup> 16% of the participants believed that only serious ADRs should be reported.

Adverse drug events (ADEs) are harmful events that are preventable if they occur due to error, whereas ADRs are noxious and unintended events that are non-preventable. Interestingly, only about a quarter of interns and pharmacists could not differentiate between ADRs and ADEs. Improvements were seen in ADRs reporting in this study (22.2% of interns and 32.1% of pharmacists) compared to previous studies where 12.5%<sup>11</sup> of community pharmacists and 26.8% of hospital pharmacists had reported ADRs.<sup>25</sup> These improvements are

**Table 2** Comparison of Good Knowledge for Different Items Between Interns and Pharmacists in Saudi Arabia (n=315)

Items	Short Names	Intern	Pharmacists
		Response (%)	Response (%)
Pharmacovigilance is the practice of monitoring the effects of medical drugs after they have been licensed for use, especially in order to identify and evaluate previously unreported adverse reactions.	K1	86.4	91.0
Which one of the following regulatory bodies regulates adverse drug reaction reporting in Saudi Arabia?	K2	76.5	80.8
There are differences between adverse drug reactions (ADRs) and adverse drug events (ADEs)	K3	69.1	72.2
I have an idea of how to report ADRs to the relevant authorities in Saudi Arabia	K4	48.1	57.7
I know the minimum information required for the submission of an initial ADRs report	K5	43.2	53.4
I know the different classifications of ADRs	K6	49.4	57.7
Hypersensitivity reactions are related to type B ADRs	K7	30.9	31.6
I know the different types of hypersensitivity reactions	K8	48.1	53.8
Which type of ADR is recommended to be reported?	K9	66.7	72.2
Type A ADRs are uncommon and unpredictable, depending on the known pharmacology of the drug; they are independent of dose and only affect few people	K10	28.4	30.3

justified by the enhancement of the mechanism of ADRs reporting and the availability of both online and paper reporting forms in the majority of the hospitals in Saudi Arabia. In addition, the ADRs reporting process is part of the requirements for national and international accreditations for hospitals.

**Table 3** Comparison of Good Perception for Different Items Between Intern and Pharmacists in Saudi Arabia (n=315)

Items	Short Names	Intern	Pharmacists
		Responses (%)	Responses (%)
Have you ever reported an ADR?	P1	22.2	32.1
I believe that the topic of pharmacovigilance is well covered in my pharmacy school curriculum	P2	29.6	35.9
I think ADRs reporting is important	P3	86.4	87.2
I believe that I have acquired enough knowledge during my undergraduate study to enable me to report ADRs	P4	30.9	35.5
With my present knowledge, I am very well prepared to report any ADRs that I face in my future practice	P5	39.5	49.6
I believe that I have acquired enough knowledge during my internship to enable me to report ADRs	P6	38.3	41.0
Majority of ADRs reports should come from pharmacists	P7	56.8	50.0
ADRs reporting should be made mandatory for all pharmacists	P8	74.1	64.5
I believe that ADRs caused by herbal medicines should be reported	P9	85.2	81.6
I must advise any patient to immediately report any ADR	P10	80.2	78.6
I believe serious and unexpected reactions that are not fatal or life-threatening during clinical trials must not be reported	P11	14.8	16.2

## Strength and Limitations of the Study

The major strength of this study is that it focused on an issue that has not been adequately studied, especially in Saudi Arabia. The comparative nature of this study differentiates it from other published studies on pharmacovigilance. However, there are some limitations. The main limitation of this study that it is a cross-sectional study, so the causality could not be warranted. Secondly, the study was based on a self-reported questionnaire, so personal bias may have affected the results.

**Table 4** Comparison of Knowledge and Perception Between Intern and Pharmacists About Pharmacovigilance in Different Health-Care Settings, Saudi Arabia

Attribute	Group (n)	Mean Score (SD)	Mean Difference (95% CI)	p-value*
Knowledge	Intern (81)	31.22 (6.01)	1.44 (0.046, 2.84)	0.043
	Pharmacists (234)	32.67 (5.34)		
Perception	Intern (81)	35.49 (5.72)	0.61 (-0.91, 2.11)	0.431
	Pharmacists (234)	36.10 (6.03)		

**Note:** \*Independent sample t-test.

## Conclusion and Recommendation

Based on this survey, it was found that there are poor awareness and knowledge of ADRs reporting among pharmacists as well as pharmacy interns. However, most of the responders believe that ADRs reporting is important and must be done by pharmacists. Therefore, it is suggested to add a pharmacovigilance course in the curriculum of pharmacy colleges in Saudi Arabia. It is also recommended that education and training programs are implemented for practicing pharmacists to enhance knowledge and perception regarding pharmacovigilance and ADRs reporting.

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## Disclosure

The authors report no conflicts of interest in this work.

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