

Evaluation of Knowledge, Awareness, and Practice of Adverse Drug Reactions at Aseer Central Hospital in Saudi Arabia

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Abstract: The purpose of this research was to evaluate the knowledge, attitude, and practices (KAP) of the healthcare professionals (HCPs) about pharmacovigilance in Aseer Central Hospital in Saudi Arabia. A cross-sectional study was conducted using a pretested questionnaire. The questionnaire was designed to assess the KAP regarding pharmacovigilance procedure. The HCPs including physicians, nurses, and pharmacists, working in the Aseer Central Hospital participated in the research. Consents were first distributed to the HCPs and only those who gave their consents to were included in the research. The data were analyzed by using the Statistical Package for Social Sciences (SPSS) statistical software, version 22.

The results showed that the majority of the healthcare professionals had good knowledge and attitude regarding pharmacovigilance and understand the necessity of reporting ADRs. However, the rate of reporting ADRs by the HCPs was remarkably low. There was a big gap between the ADRs experienced and ADRs reported by the participant HCPs. It was also found that there is a positive correlation between the training of pharmacovigilance and reporting ADRs reporting. It was realized that the majority of respondents agreed that reporting of ADRs was necessary and also were aware that pharmacovigilance should be taught in detail to healthcare professionals as that they have started to understand the importance of pharmacovigilance.

Keywords: Adverse drug reactions, attitude, knowledge, pharmacovigilance, practice, spontaneous reporting, underreporting.

Introduction

Adverse drug reactions (ADRs) have been globally recognized as an important cause of morbidity and mortality. (WHO) defined ADR is any noxious, unintended, and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or therapy. The impact of ADR on socio-economic and health consequences have been investigated in several studies⁽¹⁾.

Similar to many nations, all HCPs including medical doctors, nurse, and pharmacists in the Kingdom of Saudi Arabia, are obliged to report an ADR by filling an ADR form of the Central Drugs Standard Control organization⁽²⁾. It is, therefore, an important issue for HCPs to know how to report and where to report an ADR. The active involvement of HCPs in the pharmacovigilance program will definitely lead to improving ADR reporting⁽³⁾. Among the several methods used in detecting ADRs, immediate reporting showed to be significant contribution to improve the levels of pharmacovigilance within healthcare settings⁽⁴⁾.

Despite the efforts of the ministry of health in implementing the pharmacovigilance programs for drug safety, yet, underreporting is still very prevalent. Therefore, it is required to provide constant training and enactment of regulations for ADR reporting among HCPs all over health care centers in the Kingdom.

Vast numbers of previous studies found that underreporting of ADRs was related to HCPs shortcomings in the knowledge, attitude, and practice⁽⁵⁾. The response of healthcare professionals (HCPs) to consider spontaneous reporting of ADRs as part of their profession is an important task to reduce the incidence of ADRs within their health care centers, so that, the development of ADR databases worldwide has been established⁽⁶⁾.

Early studies from different sites have focused on the perception and practice of ADRs reporting among physicians only while excluding other effective health care professional as pharmacists and nurses⁽⁷⁾. However, it has been proven that nurses and pharmacists have very important roles to play in patient counseling and consequent ADR monitoring and reporting⁽⁸⁾. Despite the availability of ADRs reporting centers in many developing nations, yet, ADRs under-reporting was a major problematic issue⁽⁹⁾. The efforts of the ministry of health in implementing the pharmacovigilance programs for drug safety are well recognized, yet, underreporting is still very prevalent. Therefore, it is required to provide constant training and enactment of regulations for ADR reporting among HCPs all over health care centers in the Kingdom. Vast numbers of previous studies found that underreporting of ADRs was related to HCPs shortcomings in the knowledge, attitude, and practice⁽⁵⁾.

Therefore, the primary objective of this research was to evaluate the knowledge, attitude, and practices (KAP) of the HCPs about pharmacovigilance one of the largest and reputable tertiary care hospital in Aseer region, south of the Kingdom of Saudi Arabia (KSA).

Finally, no similar research studies have been done to assess the KAP of pharmacovigilance among healthcare professional in Aseer Central Hospital. The current research included not only doctors but nurses and pharmacist who were in direct physical diagnostic, nursing and drug prescribing contacts. Other HCPs who were doing managerial or laboratory work were excluded.

Research objectives

- To assess the reasons of underreporting of ADRs as it needs to be well assessed in KSA.
- To correlate HCPs characteristics including their gender, age, professionalism and experience with their knowledge, attitude and practice in order to be acquainted with all probable factors that may contribute to ADRs reporting.

Research question

To what extent are the medical cadres aware of the practice of adverse drug reactions at Aseer central hospital in Saudi Arabia?

Literature Review

Adverse drug reactions (ADRs) have been recognized as the main cause of patients' morbidities and mortalities worldwide in healthcare settings. Up to 98,000 mortalities due to medical errors were reported in the USA on annual basis⁽¹⁰⁾. Out of this total, an estimation of 7000 deaths was related to Adverse drug reactions. An analysis conducted by the American pharmaceutical association counted up to 6000 deaths from different types of ADRs and over two million with serious side effects⁽¹¹⁾.

The risk of having ADRs are increasing by the concomitant administration of several drugs either prescription or over the counters. The severity and numbers of ADRs increase with the increase in the number of the administered drugs. The concomitant administration of several drugs is termed as polypharmacy⁽¹²⁾. The increased numbers of prescribed drugs higher the possibility of polypharmacy, however, this does not mean to stop the patients from taking take many medications when appropriate⁽¹³⁾. Drug-Drug interactions (DDIs) are defined as occurring interactions when the therapeutic effects of a specified drug are changed by the co-administration of another drug⁽¹⁴⁾. Factors as drug dose, serum drug level, route of administration, drug metabolism, duration of therapy, and patient factors, such as age, gender, weight and genetic predisposition are all significant causes of drug interactions⁽¹⁵⁾.

The development of ADRs is affected by drug dosing in a number of ways as some drugs required to be taken in the evening while others in the morning or before bedtime. For example, the antiplatelet effect of aspirin is more potent when administered in the evening than when taken in the morning. Taking bisphosphonates may lead to esophagitis when given in the evening⁽¹⁶⁾. Dosing frequency is therefore recognized as a potential factor that may lead to the development of ADRs.

Increasing the frequency of idiosyncratic toxicity with anti-infective drugs such as trimethoprim-sulphamethoxazole are an example⁽¹⁷⁾. Patients are more vulnerable to ADRs due to the presence of multiple diseases and the use of many drugs. Many diseases accompanied with hypertension might have a high impact on the response of the body to antihypertensive due to the negative effects of these diseases on the metabolic processes of the body. The effects of drugs on the kidneys are lessened in patients with renal failure, because of the loss of the active site for these drugs. This leads to increase the drug dose and consequently leads to higher risk of ADRs. Prescribed NSAIDs may lead to serious medical problems in patients with peptic ulcers⁽¹⁸⁾. Avoidance of ADRs has been an important issue in the field of pharmacovigilance studies. Many of these studies address the importance of knowledge, attitude, and practice of ADR reporting with the view of

improving ADR reporting. The role of pharmacists in the management of ADRs has been investigated⁽¹⁹⁾. The authors concluded that pharmacists showed to play a positive role in monitoring ADRs.

On the basis of professionalism, there are wide variations of HCPs within the medical team and should all participate in ensuring for the safety and efficacy of newly marketed drugs and their administration would not impact any harm on the patients. Pharmacists should regularly report ADRs to the designated health authorities in collaboration with other HCPs to help in withdrawing potentially serious drugs from the market⁽²⁰⁾. He provided useful insights for the community pharmacists to discover and report any ADRs related to over the counter products and any complementary and alternative medications. Customers who regularly come for prescription refill could be a good source to providing the pharmacists with their experienced ideas for detecting and reporting ADRs⁽²¹⁾. Based on these findings, it was recommended to create awareness system about ADRs reporting and find ways to simplify the system to make spontaneous reporting easier and more reliable. In another study⁽²²⁾ involving medical practitioners reported that professionals were aware of adverse drug reaction reporting, however, their practices were far from encouraging it, leading to under-reporting. These findings are in agreement with those which reported that HCPs in India were knowledgeable and had the positive attitude about ADRs reporting, however, their practices were not satisfactory and needed improvement⁽²³⁾.

A cross-sectional survey on the knowledge, attitude, and practice towards pharmacovigilance among Nepalian HCPs⁽²⁴⁾ found that they had the right attitude and practice, but they showed little pieces of knowledge towards ADRs and pharmacovigilance concept. It was also reported that, although the majority of HCPs were aware that, adverse drug reaction monitoring is essential, yet only a few of them had reported ADRs to the pharmacovigilance center. Although adverse drug reaction monitoring is essential, only a few ever reported them to the pharmacovigilance center. The two primary reasons for under-reporting was the lack of awareness of the existence of the reporting system and have never come across any ADR. The study concluded that there is a need for continuous educational initiatives for the health professionals to improve pharmacovigilance at the hospital.

A study from Malaysia⁽²⁵⁾ reported unsatisfactory conclusion regarding the knowledge, practices, and awareness among HCPs⁽²⁶⁾ recommended to implement ADRs in undergraduate teaching and further reinforced during students' internships so that good preparation for future HCPs with good pharmacovigilance background could be attained. There are also needs to implement ways to improve HCPs knowledge and attitudes of every health professional to enhance ADRs monitoring as part of their clinical practice⁽²⁷⁾.

Nursing was long recognized as important as doctors' practices. Nurses are to administer drugs as prescribed by the doctors. They are the closest to patients more than any HCPs. It is therefore quite appropriate that nurses must be among the first HCPs responsible to observe any changes in the condition the patients after using the drugs. A study investigated nurses' knowledge, awareness, and practice towards ADRs reporting⁽²⁸⁾. The study showed that nurses had insufficient knowledge about the purposes, and usefulness of the adverse drug reactions reporting system. In addition, their attitudes towards ADRs reporting were found low. Further training of the nurses has been recommended to improve their level of ADRs reporting⁽²⁹⁾.

However, there is still considerable research shortage in the Saudi Arabian Kingdom about the knowledge, awareness, and practices towards reporting ADRs among HCPs. The purpose of this research was, therefore, to assess HCPs knowledge, attitude and practice towards ADRs reporting with the purpose to draw efficient ADRs program for the HCPs in Aseer region, KSA in order to enable them to be acquainted with efficient ADRs reporting tools and procedures.

Method and Procedures

Research Design and Sample

The researcher sample included 230 of workers at Aseer Central Hospital (ACH) where 189 successfully responded and filled out the questionnaires completely; the return percentage is 82.17%

Cross-sectional study was conducted using a questionnaire containing 20 modified Multiple-Choice Questions "MCQ" (4 questions) detailed socio-demographic questions related to the healthcare practitioners (HCPs) plus (7 questions) concerning the knowledge, attitude (4 questions) and practice (4 questions) of the "HCPs" towards Adverse Drug Reactions "ADRs"⁽³¹⁾. One question was asked to determine the reasons for under-reporting of ADRs. The validity of the questionnaires was determined using Cronbach Alpha (Cronbach Alpha = 0.648). It is a value used to determine the validity of the studied questions. The obtained value was > 0.6 which means that the questions were valid.

Pretesting of the 20 questions in the questionnaire was done on 20 randomly selected HCPs working in the hospital. The questionnaire was finalized after ambiguous and unsuitable questions were modified based on the result of the pretested questionnaire. This questionnaire was designed based on previous studies for assessing KAP of ADR reporting. Questionnaire Adapted from Gupta et al. (2015).

The study was conducted at ACH, which is the biggest tertiary care hospital in Aseer Region, south of the Kingdom of Saudi Arabia

The socio-demographic characteristics include the HCPs gender, Age, profession (physicians, pharmacists, and nurses) and years of experience.

Statistical analysis

Information from the returned pretested questionnaire was coded and entered into Statistical Package for Social Sciences (SPSS) version 22 software. Spearman's correlation was used to determine any relationship between the training of pharmacovigilance and reporting ADR. Logistic regression analysis was also employed to find the correlation between participant's characteristics in terms of gender, age, profession (physicians, pharmacists, and nurses) and their knowledge, attitude and practice regarding adverse drug reaction.

Results

Baseline characteristics of the study participants

The socio-demographic characteristics of the participant healthcare professionals (HCPs) working in Aseer central hospital (ACP) are presented in Table 1 and further illustrated in Figures 1 - 4. Involved HCPs were the physician, pharmacists, and nurses. Two hundred and thirty questionnaires were distributed among the HCPs, however, 189 with a rate of 82% of the questionnaires were returned. The majority were females (n= 102, 54%) since the center employs too many nurses to ensure the proper delivery of health services and most of the nurses are females. Most of the participants' age was between 30 – 50 years (66%) compared with 20.6% and 13.7% of the ages < 30, and > 50 respectively. The majority of the participants were females (n= 102, 54%). The majority of the participants were nurses (n = 89, 47%) followed by the physicians (n = 61, 32.4%) while the least participants were pharmacists as the number of employed pharmacists is too little. Regarding the participant's experience, it is seen from Table 1 that, 35.6% was the highest rate the highest rate of experience of between 11 – 20 years, followed by a rate of 28.4% with experience between 5 -10 years. The least rates of 18,9% and 17.1% were fore experiences <5 years and > 20 years respectively.

Table (1) Socio-demographic Characteristics of Medical Team Participants

Socio-demographic variables	Frequency	Percentage
Gender:		
Males	87	46%
Females	102	54%
Total Participants	189	
Age in Years:		
< 30	39	20.6%
From 30 – 40	58	30.7%
From 41 – 50	66	35.0%

Socio-demographic variables	Frequency	Percentage
> 50	26	13.7%
Profession Status:		
Physicians	61	32.4%
Pharmacists	39	20.6%
Nurses	89	47%
Experiences in Years:		
< 5 Years	36	18.9%
5 – 10 Years	54	28.4%
11 – 20 Years	67	35.6%
> 20 years	32	17.1%

Knowledge

The results in Table 2, showed that 111 (58%), of the participated healthcare professionals (HCPs), correctly answer question No.1 regarding pharmacokinetic definition. The results in Table 2 also indicate that 70.2% of the HCPs were aware that, identifying medication safety is the most important purpose of pharmacovigilance. On the other hand, up to 74.1% of the participants agreed that ADRs reporting is a professional obligation for them. The vast majority (89.4%) agreed that reporting of ADRs in the hospital must be the responsibility of all HCPs including physicians, nurses, and pharmacists of the participants, and a rate of 83.1% was acknowledged with the existence of the National Pharmacovigilance Program in the Kingdom of Saudi Arabia. 76.2% of the HCPs were aware with the regulatory body responsible for monitoring ADRs in Saudi Arabia as being the Saudi Food and Drug Administration (SFDA). About the location of the international center for ADRs monitoring fewer rate (38%) of the participants correctly answered to be in Sweden.

Table (2) Frequency and percentages of HCPs Regarding their ADRs Knowledge

Questions Related to HCP Knowledge	Right Answers		Wrong Answers	
	Frequency	Percent	Frequency	Percent
Pharmacovigilance is defined as	111	58.7%	78	41.3%
2. Important Purposes of Pharmacovigilance include	132	70.2%	57	29.8
3. Do you consider ADR reporting a professional obligation for you?	140	74.1%	49	25.9%
4. Responsible Healthcare personal to reporting ADRs in a hospital is/are	169	89.4%	20	10.6%

Questions Related to HCP Knowledge	Right Answers		Wrong Answers	
	Frequency	Percent	Frequency	Percent
5. Have you ever heard about the National Pharmacovigilance Center in Saudi Arabia?	157	83.1%	32	16.9%
6. In Saudi Arabia which regulatory body is responsible for monitoring ADRs?	144	76.2%	45	23.8%
7. Where is the international center for ADRs monitoring located?	72	38.0%	117	62.0%

ADRs = Adverse Drug Reactions HCPs = Health Care Practitioners

Attitude

Table 3 is a presentation of the frequency and percentages of The HCPs in the present study regarding their attitudes towards ADRs. A total of 146 (77.1%) of the participants that, establishing an ADRs monitoring center in every hospital is an essential request for better drug safety and consequent healthcare management. Up to 179 (94.7%) of the participants positively agreed that pharmacovigilance should be comprehensively taught in details to all HCPs to ensure medication safety. On the other hand, 131 (69.3%) reported positive response that they have been reading articles relating to ADRs, while, a sum of 185 (97.9%) agreed for the importance of reporting ADRs.

Table (3) Frequency and percentages of HCPs Regarding their ADRs Attitudes

Questions Related to HCP attitude	Right Answers		Wrong Answers	
	Frequency	Percent	Frequency	Percent
8. What is your opinion about establishing ADR monitoring center in every hospital?	146	77.1%	43	22.8%
9. Do you think Pharmacovigilance should be taught in detail to healthcare professionals?	179	94.7%	10	5.3%
10. Have you read at any time an article on prevention of adverse drug reactions?	131	69.3%	58	30.7%
11. Do you think reporting of ADR is necessary?	185	97.9%	4	2.1%

ADRs = Adverse Drug Reactions HCPs = Health Care Practitioners

Practice

The results in Table 4 include the frequency and percentages of the HCPs regarding their practice towards ADRs. It is shown that 130 (68.8%) participants reported having experienced ADRs in patients during their practice, however, only 38 (20.1%) have ever reported ADRs cases to pharmacovigilance centers. Merely 94 (49.7%) participants were aware of having an idea about how an ADRs form looks like. Only 95 (50.3%) of the HCPs reported being trained on how to report ADR cases.

Table (4) Frequency and percentages of HCPs regarding their Practice towards ADRs.

Questions Related to HCP Practices	Yes		No	
	Frequency	Percent	Frequency	Percent
12. Have you experienced any ADRs with your patients during your practice?	130	68.8%	59	31.2%
13. Have you ever reported ADRs to the Pharmacovigilance center?	38	20.1%	151	79.9%
14. Do you have any idea about ADRs reporting form?	94	49.7%	95	50.3%
15. Did you experience any training on how to report ADRs?	95	50.3%	94	49.7%

ADRs = Adverse Drug Reactions HCPs = Health Care Practitioners

Reasons for under reporting

The factors discouraging participants from reporting ADRs were no remuneration (31.7%), lack of time to report ADR (23.8%), believe that a single unreported case may not affect ADR database (21.8%), and difficulty to decide whether ADR has occurred or not (22.8%).

The Correlation between pharmacovigilance training and ADRs reporting was analyzed by the use of Spearman’s correlation coefficient. The results of the analysis in Table 5, shows medium and positive correlation coefficient between pharmacovigilance training and ADRs reporting by the participated HCPs ($r = 0.401$, $n = 189$ and $p < 0.001$) reporting ADRs.

Table (5) Spearman’s correlation Coefficient between Pharmacovigilance training and ADRs reporting

Statement	Have you been trained to report ADR?	Have you ever reported ADRs to PHV Center?
Have you been trained SP.C to report ADR? Sig. (2- tailed)	1	0.401** 0.001

Statement	Have you been trained to report ADR?	Have you ever reported ADRs to PHV Center?
<i>n</i>	189	189
Have you ever reported P.C ADRs to PHV Center? Sig. (2- tailed)	0.401** 0.001	1
<i>N</i>	189	189

ADR = Adverse Drug Reaction
SP.C. = Spearman’s correlation coefficient
PHV = Pharmacovigilance

Table (6) Binary Logistic Regression between knowledge and HCPs characteristics

Characteristics	B	P value	OR	95 % CI	
				Lower	Higher
Gender:					
Males	0.241	0.387	1.134	0.753	2.054
Females					
Total Participants					
Age in Years:					
< 30	-0.012	0.385	0.998	0.976	1.025
From 30 – 40					
From 41 – 50					
> 50					
Profession Status:					
Physicians	1.026	0.002	2.778	1.412	5.75
Pharmacists					
Nurses					
Experiences in Years:					
< 5 Years	1.021	0.009	2.815	1.311	6.041
5 – 10 Years					
11 – 20 Years					
20 years					

B = Regression Coefficient (positive values indicate higher probabilities and negative values indicate lower probabilities, OR = Odds Ratio, 95% CI = Confidence Interval, p value significance at < 0.05

Table 6: illustrate the binary logistic regression data between HCPs covariate and their knowledge regarding ADRs. There was significant association between the knowledge and the HCPs professionalism (physicians, nurses and pharmacists) and years of experiences with respective values of (P = 0.002, OR 2.778, CI = 1.412-5.75) and (p = 0.009, OR = 2.815, CI = 1.311-6.041), While the values for the HCPs gender and age showed no significant difference in their knowledge with respective values of (p = 0.387, OR = 1.134, CI = 0.753-2.054) and (p = 0.385, OR = 0.998, CI = 0.976-1.025).

Table (7) Binary Logistic Regression between attitude and HCPs characteristics

Characteristics	B	P value	OR	95 % CI	
				Lower	Higher
Gender:					
Males					
Females	0.204	0.278	1.103	0.653	2.154
Total Participants					
Age in Years:					
< 30					
From 30 – 40	-0.022	0.394	0.898	0.966	1.014
From 41 – 50					
> 50					
Profession Status:					
Physicians					
Pharmacists	1.011	0.001	2.778	1.412	6.75
Nurses					
Experiences in Years:					
< 5 Years					
5 – 10 Years	1.029	0.007	2.724	1.368	8.041
11 – 20 Years					
20 years					
B = Regression Coefficient (positive values indicate higher probabilities and negative values indicate lower probabilities, OR = Odds Ratio, 95% CI = Confidence Interval, p value significance at < 0.05					

Regarding the Binary Logistic Regression between attitude and HCPs characteristics in Table 7, the data agreed with that for the knowledge in Table 6 and the data for the relation to the attitude were significantly correlate for the professional status (physician, nurses and pharmacists) and for the years of

experiences with respective values of ($p = 0.001$, OR = 2.778, CI = 1.412-6.75) and ($p = 0.007$, OR 2.724, CI = 1.368-8.041). On the other hand, the effect of gender and age were not significant with respective values of ($p = 0.278$, OR = 1.103, CI = 0.653-2.154) and ($p = 0.394$, OR = 0.898, CI = 0.966-1.014).

Table (8) Binary Logistic Regression between Practice and HCPs characteristics

Characteristics	B	P value	OR	95 % CI	
				Lower	Higher
Gender:					
Males					
Females	0.216	0.367	1.200	0.554	2.045
Total Participants					
Age in Years:					
< 30					
From 30 – 40	-0.518	0.494	0.706	0.166	1.985
From 41 – 50					
≥50					
Profession Status:					
Physicians					
Pharmacists	1.311	0.001	2.878	1.912	8.75
Nurses					
Experiences in Years:					
< 5 Years					
5 – 10 Years	1.038	0.002	2.924	1.556	9.143
11 – 20 Years					
≥20 years					
B = Regression Coefficient (positive values indicate higher probabilities and negative values indicate lower probabilities, OR = Odds Ratio, 95% CI = Confidence Interval, p-value significance at < 0.05					

The Binary Logistic Regression between Practice and HCPs characteristics are shown in Table 8. Again, the data seems to agree with those in Table 6 and 7 as there were significant differences between HCPs profession and experiences regarding their practice with values of ($P = 0.001$, OR = 2.878, CI = 1.912-8.75) and ($p = 0.002$, OR = 2.924, CI = 1.556-9.143). Both the HCPs gender and age showed no significant difference on their practice and the respective values were ($p = 0.367$, OR = 1,200, CI = 0.554-2.045) and ($p = 0.494$, OR = 0.706, CI = 1.66-1.985)

The data in Tables 6, 7 and 8 showed that both HCPs Professionalism (physicians, nurses, and pharmacists) and their years of experiences were significantly more likely to affect their knowledge's, attitudes and practices rather than their gender and/or age.

Discussion

The results of the present investigation in terms of HCPs knowledge, attitude and practice were compared with some previous reports in Table 9 and found comparable.

Table (9) Comparison with some previous works on HCPs knowledge, attitude and practice regarding ADRs.

Knowledge Related Questions	Present Work %	Sandeep K. et al (2017) ³²	Rajesh R, et al (2011) ³³	Khan SA, et al (2013) ³⁴
Definition of pharmacovigilance.	58.7%	62.4%	55.2%	NA
ADR reporting is a professional obligation.	74.1%	69.3%	89.4%	66.2%
The existence of pharmacovigilance program in Saudi Arabia reporting system.	83.1%	75.2%	NA	69.1%
Attitude Related Questions				
Reporting of adverse drug reaction is necessary.	97.9%	97%	91.8%	95.6%
Pharmacovigilance should be taught to healthcare professionals.	94.7%	92.1%	94.1%	NA
ADR monitoring center should be established in every hospital.	77.1%	74.3%	70.6%	NA
Practice Related Questions				
Ever experienced ADRs During practice.	68.8%	64.4%	NA	NA
Ever reported any ADR.	20.1%	22.8%	NA	19.1%
HCPs training on how to report ADR.	50.3%	53.5%	50.5%	25%

The results in the present studies revealed that vast number of the healthcare professionals "HCPs" agreed on the necessity to reporting ADRs in regular bases with the implementation of detailed pharmacovigilance as a necessity that acknowledges HCPs on how to detect and report ADRs. In this study,

there was a remarkable difference between the HCPs experience on ADRs during practicing within their patients (68.8%) and the percentage of those who actually reported ADRs (20.1%). The factors responsible for underreporting were also determined in this study. The determinants of underreporting, from our study include, lack of time to report ADRs, believe that a single unreported case may not affect ADRs database. Other reasons were lack of training, unawareness regarding the ADRs reporting form, ignorance of the rules, and procedure for reporting. A comparison with the results of the published studies on HCPs response regarding ADRs, KAP seen in Table 9 demonstrated that knowledge and attitude towards pharmacovigilance are improving among healthcare professionals, but unfortunately the actual practice of ADRs reporting is still deficient among them.

Socio-demographic characteristics of the gender, age, professionalism (Physician, nurses, pharmacists) in addition to their years of experiences have shown to have a variable effect on the participants' knowledge, attitude and practice (KAP).

The regression results indicated that neither gender nor age have a significant difference on the participant's response to KAP and do not seem as major predictors in this situation. On the contrary, participants professionalism showed significantly different responses in KAP. The reason could be attributed to that, physicians are rather exposed to their patients during diagnosis of their illnesses and prescribing the medication so that, they are more acquainted to recognize any complication or side effects to report as ADRs. Nurses are also in close contact hospitalizing the patients but maybe in a lesser degree than the physician so that; they could have a moderate response to ADRs. About the pharmacists, their contact with their patients is tangential to handling them their prescribed medication without any positive communication about the patient case.

The years of experiences seem to effectively participate in the degree of KAP. The explanation of that could be related to that, as the participant had extended experience dealing with the patients and exposed to similar cases for long period of time they may be able to realize and guess for any abnormal thing or behavior on the patient condition and consider it as a sort ADRs that required to be reported as a case study. The study highly recommends putting more power into implementing well-designed pharmacovigilance course to all HCPs especially those young HCPs and those belonging to the hospital and clinical pharmacists.

Other reasons were lack of training, unawareness regarding the ADRs reporting form, ignorance of the rules, and procedure for reporting. The comparison with the results of published studies demonstrated that knowledge and attitude towards pharmacovigilance are gradually improving among healthcare professionals, but unfortunately the actual practice of ADR reporting is still deficient among them. The

adverse event reporting rate from our study is low which is similar to previously reported results of Hardeep et al. (2013)⁽³⁵⁾.

Most importantly, the huge gap between the ADR experienced and ADR reported by the healthcare professional was also evident in previously reported studies conducted in the study of Pimpalkhute, *et al.* (2012)⁽³⁶⁾. In our study, less percentage of participants had ever been trained on reporting ADRs which is similar to the low percentage of training imparted to healthcare professionals in previously reported results from the study of Khan *et al.* (2013)⁽⁵⁾.

The current study reemphasized the fact that there is a positive correlation between the training of pharmacovigilance and reporting ADRs by the healthcare professional and it demonstrated that the significance of adverse event monitoring and reporting can be increased through academic interference. Factors such as the unawareness about the method to decide the causal relationship between the ADRs can only be removed by regular training⁽³⁷⁾.

Conclusion

Out of 230 pretested questionnaires, a total of 189 (82.17%) HCPs were respondent. 58.7% of healthcare workers gave a correct answer regarding the definition of pharmacovigilance. 83.1% of HCPs were aware regarding the existence of a National Pharmacovigilance Program of in the Kingdom of Saudi Arabia. 74.1% healthcare professional agreed that ADR reporting is a professional obligation. On the other hand, 68.8% have experienced ADRs in patients, however, only 20.1% were able to report ADRs to pharmacovigilance center. Incidentally, only 50% of healthcare workers have been trained for reporting adverse reactions. Fortunately, 97.9% of healthcare professionals agreed that reporting of ADRs are necessary and 94.7% were of the view that pharmacovigilance should be taught in detail to the healthcare professional. Regarding the effect of HCPs characteristic on the degree of response to the knowledge, attitude and practice (KAP), Binary logistic regression showed that, HCPs gender and age seemed to be insignificantly correlated in their response towards the KAP ($p = > 0.05$), however, both professionalism (being physicians, Nurse or pharmacists) and the years of experience were significantly correlated. Spearman's correlation coefficient showed a medium and positive correlation between pharmacovigilance training and ADRs reporting by the participants ($r = 0.401$, $n = 189$ and $p < 0.001$).

The researcher suggests teaching pharmacovigilance for the undergraduates and to develop a curriculum for healthcare professionals. Besides, it is recommended to organize regular training on pharmacovigilance including adverse drug reaction (ADR) reporting. Finally, it is preferable to establish a network of doctors for ADR reporting.

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تقييم معرفة وسلوكيات وممارسات أخصائي الرعاية الصحية فيما يتعلق بسلامة الأدوية،
وذلك في مستشفى عسير المركزي في العربية السعودية

الملخص: هدف هذا البحث بشكل أساسي إلى تقييم معرفة وسلوكيات وممارسات أخصائي الرعاية الصحية فيما يتعلق بسلامة الأدوية أو الصيدلة الاحتراسية، وذلك في مستشفى عسير المركزي في السعودية حيث تم إجراء دراسة مقطعية وذلك باستخدام استبانة تم تطويرها واختبارها قبل توزيعها من أجل تقييم الممارسات الطبية فيما يتعلق بإجراءات سلامة الأدوية. وشملت الدراسة كلاً من الأطباء والمرضى والصيدلة العاملين في مستشفى عسير المركزي. وقد تم توزيع الاستبانات على الأشخاص المذكورين والذين وافقوا على المشاركة في الدراسة، وبعد ذلك تم تحليل البيانات باستخدام برنامج التحليل الإحصائي SPSS الإصدار 22.

وأظهرت النتائج أن غالبية أخصائيي الرعاية الصحية لديهم معرفة وسلوكيات جيدة فيما يتعلق بتفاعلات الأدوية وتفهمهم لضرورة الإبلاغ في حال وجود تفاعلات دوائية ضارة. وعلى الرغم من ذلك، معدل الإبلاغ عن التفاعلات الدوائية الضارة من قبل إخصائيي الرعاية الصحية كان منخفضاً بشكل ملحوظ. كما كان هناك فجوة كبيرة بين التفاعلات الدوائية الضارة التي حدثت وبين عدد مرات الإبلاغ عنها. وتبين أيضاً وجود علاقة إيجابية بين التدريب على الصيدلة الاحتراسية والإبلاغ عن التفاعلات الدوائية. وأظهرت النتائج موافقة غالبية المستجيبين على ضرورة الإبلاغ عن التفاعلات الدوائية الضارة، وتبين وجود وعي كبير من قبلهم بهذا الشأن، إلى جانب تأكيد المستجيبين على ضرورة تدريس الصيدلة الاحتراسية والتفاعلات الدوائية الضارة بشكل مفصل لأخصائيي الرعاية الصحية.

الكلمات المفتاحية: التفاعلات الدوائية الضارة، سلوكيات أخصائيي الرعاية الصحية، التأثيرات الدوائية، عدم الإبلاغ.