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Knowledge, Attitude and Practice of Pharmacovigilance in Healthcare Professionals and Medical Students in Majmaah, Saudi Arabia Care Centre

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ABSTRACT

Background: *Adverse drug reactions (ADRs) are one of the major reasons of morbidity and mortality all over the world. The knowledge of ADRs is essential for healthcare professionals as they are in contact with the patients and can effectively detect the ADRs.* ***Purpose of the study:*** *To evaluate the knowledge, attitude, and practice of pharmacovigilance in healthcare professionals and medical students in Majmaah, KSA.* ***Methods:*** *This was a cross-sectional questionnaire-based study. The health care professionals of Al-Majmaah, i.e., doctors, nurses, pharmacists including the medical students were included in the study.* ***Results:*** *Total 148 participants were included in the study, 89% of these were male and 11% were females. Overall the knowledge and awareness regarding pharmacovigilance and ADRs was low ranging from 27% to 64.2%. There was a consensus among the healthcare professionals including the medical students that reporting of the ADRs is necessary and it should be taught in detail to them denoting a positive attitude. Overall reporting rate for ADRs was only 35.1% even though the percentage of professionals who encountered the ADRs was 52.7%.* ***Conclusion:*** *Findings of this study point us towards an important aspect of medicinal safety that is lack of knowledge about the adverse drug reactions and their reporting in doctors, nurses, pharmacists, and medical students. The lack of knowledge also reflects on their practice of not reporting the ADRs adequately.*

Keywords: Pharmacovigilance, Healthcare, Saudi Arabia, Adverse drug reactions

INTRODUCTION

Pharmacovigilance is defined as the science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug related problems [1]. Adverse drug reaction is a noxious, undesirable, and unintended effect that occurs because of drug treatment at doses normally used in man for diagnosis, prophylaxis, and treatment [2]. Adverse drug reactions are associated with significant morbidity and mortality [3,4]. It has been estimated that 6.5% of acute hospital admissions are due to ADRs [5]. And that one in seven hospital inpatients experience an ADR [6].

Voluntary spontaneous reporting has contributed significantly to successful pharmacovigilance. The contribution of medical health care professionals, in this regard, is enormously significant and has encouraged ongoing ascertainment of the benefit-risk ratio of some drugs [7,8].

The National Pharmacovigilance and Drug Safety Centre is functioning under the Saudi food and drug authority (SFDA) and is known as Saudi Vigilance. For the success of this national programme knowledge of ADRs and ADR reporting is essential in all health care professionals and budding doctors. Most of the young doctors and medical

students have neither seen the adverse drug reaction (ADR) form issued by Saudi Vigilance nor are they aware of the procedure to report an ADR.

One of the most difficult aspects of ADR monitoring is to foster a culture of reporting among the clinicians, especially among the junior doctors, as they are more closely associated with the patient care. At present the ADR reporting is low mainly due to lack of awareness and training and time constraints [9]. The studies evaluating the knowledge, attitude, and practice regarding ADR reporting are limited. A few studies carried out in Kingdom of Saudi Arabia have shown poor knowledge, attitude, and deficient practices of ADR reporting among the prescribers and healthcare professionals [9-11].

Hence this study was planned to evaluate the knowledge, attitude and practice of the healthcare professionals including physicians, nurses, pharmacists, and medical students as all of them can report adverse drug reactions.

METHODS

This cross-sectional study was conducted in government and private hospitals, primary healthcare centers, medical colleges and among other healthcare providers in Majmaah city, Kingdom of Saudi Arabia. The target population consisted of doctors, nurses, pharmacists, and medical students. Complete enumeration method was used to collect the data.

A pretested, preformed questionnaire assessing knowledge, attitude, and practice was used to collect data from the participants in a time bound manner. This questionnaire was prepared taking into consideration the previously conducted studies [12-14]. Data was entered in the SPSS software version 17, the frequency and percentages of right answers for knowledge were calculated and the frequency and percentage of participants responding positively to the questions of attitude and practice were evaluated. Pearson's correlation test was used to evaluate the correlation between the responses of the participants and their profession.

Inclusion Criteria

All the healthcare professionals' i.e., doctors, nurses, and pharmacists from government hospitals as well as private hospitals were included in the study. All medical students in clinical phase (third year and onwards) were also included in the study.

Exclusion Criteria

Any study participants who voluntarily refuse to participate in the study were excluded. First and second year medical students were excluded from the study as they have no exposure to pharmacovigilance and adverse drug reaction monitoring which is taught during second semester of the course.

RESULTS

The questionnaire was distributed to more than 250 healthcare professionals including medical students. Only 148 participants returned the filled questionnaire back. The gender distribution was 131 males and 17 females. Out of these 148 participants, 18 (12.16%) were doctors, 25 (16.89%) were pharmacist, 42 (28.39%) were nurses and 63 (42.56%) students. The results are mentioned in the Table 1 below.

Table 1 Knowledge related questions and frequency of correct responses (N (%))

Questions	Doctors	Pharmacist	Nurses	Students	Total
Definition of Pharmacovigilance	9 (50%)	5 (20%)	6 (14.3%)	20 (31.7%)	40 (27%)
Functions of Pharmacovigilance	9 (50%)	14 (56%)	22 (52.4%)	25 (39.7%)	70 (47.3%)
Pharmacovigilance includes? (components of Pharmacovigilance)	7 (38.9%)	10 (40%)	19 (45.2%)	18 (28.6%)	54 (36.5%)
National pharmacovigilance program in Saudi Arabia is governed by? (Regulatory authority)	11 (61.1%)	20 (80%)	23 (54.8%)	41 (65.1%)	95 (64.2%)
Adverse Drug Reactions (ADR) can be defined as?	9 (50%)	19 (76%)*	19 (45.2%)	36 (57.1%)	83 (56.1%)
ADRs which are independent can be treated?	11 (61.1%)	10 (40%)	20 (47.6%)	24 (38.7%)	65 (43.9%)
Augmented drug reaction is?	7 (38.9%)	7 (28%)	7 (16.7%)	20 (31.7%)	41 (27.7%)

Which one of the following is the "WHO online databases" for reporting ADRs?	4 (22.2%)	3 (12%)	8 (19%)	17 (27%)	32 (27.7%)
The health care professionals responsible for ADR reporting in a hospital is/are?	8 (44.4%)	13 (52%)	15 (35.7%)	35 (55.6%)*	71 (48%)
*p<0.05 significant					

Table 1 shows the knowledge of pharmacovigilance in healthcare providers and students. Only 27% of the participants were aware of the definition of pharmacovigilance. The highest knowledge for definition of pharmacovigilance was recorded in doctors (50%) and the nurses had least knowledge about it. About 47.3% of the participants knew the function of pharmacovigilance, highest (56%) was among pharmacists and lowest was in the students with 39.7%. Around 36.5% participants had knowledge about the components of pharmacovigilance the highest 45.2% seen in nurses and lowest in 18 students 28.6%. About 64.2% participants had knowledge that the Saudi food and drug authority (SFDA) controls the National pharmacovigilance program in Kingdom of Saudi Arabia, the pharmacists (80%) had highest knowledge about this aspect and only 54.8% nurses were aware of this fact.

Regarding the definition of adverse drug reaction (ADR) 56.1% participants could recall the definition of adverse drug reaction, highest recorded within the pharmacists (76%) which was significantly higher than others and lowest recorded within the nurses 45.2%. About 43.9% participants could answer correctly about adverse drug reaction (ADR) management, as expected it was highest in the doctor's (61.1%) and lowest in the students (38.7%).

Only (27.7%) participants knew the definition of augmented drug reaction, it was high within the students (31.7%) and least in the nurses (16.7%). Only 21.6% participants knew that Vigibase is the WHO online database for reporting an adverse drug reaction, the highest knowledge was in students (27%) and the lowest in pharmacists (12%). Regarding who can report an adverse drug reaction (ADR) (48%) participants were right, the students had highest knowledge in this regard (55.6%) and lowest in doctors (44.4%).

Table 2 Frequency and percentage of positive responses for attitude related questions on ADR reporting (N (%))

Questions	Doctors	Pharmacists	Nurses	Students	Total
Reporting of ADR is a professional obligation to you?	12 (66.7%)	14 (56%)	27 (64.3%)	35 (55.6%)	88 (59.4%)
ADR monitoring centre should be in every hospital	14 (77.8%)	18 (72%)	34 (81%)	33 (52.4%)	99 (66.9%)
Reporting of ADRs is necessary?	15 (83.3%)	25 (100%)***	21 (50%)	49 (77.8%)	110 (74.3%)
Pharmacovigilance should be taught in detail to healthcare professionals?	12 (66.7%)	24 (96%)*	28 (66.7%)	51 (81%)	115 (77.7%)
*p<0.05; ***p<0.0005					

Table 2 shows the affirmative responses of the healthcare professionals and students for the questions related to attitude. When the healthcare professionals and students were asked whether they think reporting ADR is a professional obligation 59.4% responded in affirmative. The highest positive response was from doctors (66.7%) and the least percentage for students (55.6%). About 66.9% of healthcare professionals affirmed that ADR monitoring center should be in every hospital. The highest percentage for healthcare professionals who think ADR monitoring center should be in every hospital were doctors (77.8%) and least in students (52.4%).

Around 74.3% of total participants felt that reporting of ADRs is necessary. The number was highest (100%) in pharmacists, which was statistically highly significant and only 50% of the nurses felt that ADR reporting is necessary. About 77.7% of total respondents affirmed that pharmacovigilance should be taught in detail to healthcare professionals. This was highest in pharmacists (96%), statistically highly significant and least in doctors (66.7%).

Table 3 Frequency and percentage of positive responses for practice-based questions on pharmacovigilance (N (%))

Questions	Doctors	Pharmacist	Nurses	Students	Total
Have you ever come across with an ADR?	9 (50%)	18 (72%)	22 (52.4%)	32 (50.8%)	81 (54.7%)
Have you come across any patient experiencing ADRs?	12 (66.7%)	14 (56%)	19 (45.2%)	33 (52.4%)	78 (52.7%)
Have you ever attended an educational session about pharmacovigilance?	8 (44.4%)	16 (64%)	19 (45.2%)	32 (50.8%)	75 (50.7%)
Have you read any article on prevention of ADRs?	9 (50%)	17 (68%)	20 (47.6%)	27 (42.9%)	73 (49.3%)

Have you ever been trained on how to report ADRs?	7 (38.9%)	18 (72%)*	16 (38.1%)	26 (41.3%)	67 (45.2%)
Non-medical person can report ADR to a nearby Healthcare professional?	11 (61.1%)	19 (76%)	31 (73.8%)	38 (60.3%)	99 (66.9%)
Have you ever reported an ADR?	7 (38.9%)	9 (36%)	11 (26.2%)	25 (39.7%)	52 (35.1%)
*p<0.05					

Table 3 shows the affirmative responses of the participants for the practice related questions. Out of 148 participants only 54.7% had experienced in ADR, 52.7% had come across patient experiencing ADRs. Only 50.7% of the participants had attended the educational session about pharmacovigilance this was maximum in pharmacists (64%) and least in doctors (44.4%). Only 49.3% of participants had read an article about pharmacovigilance this was also maximum in pharmacists (68%) and least in medical students (42.9%). The percentage of healthcare professionals trained for reporting ADRs was 45.2% and pharmacists (72%) were most trained (statistically significant) in this aspect and least in nurses (38.1%). About 66.9% of the participants were aware that non-medical person can report ADR this was highest in pharmacists (76%) and least in medical students (60.3%). The reporting of ADRs was done by only 35.1% participants maximum reporting was by medical students (39.7%) and least by the nurses (26.2%).

Table 4 Correlation between the profession and responses of health care professionals to the knowledge-based questions of pharmacovigilance

Questions	Pearson Chi-Square test (p-value)
Definition of Pharmacovigilance	0.088
Functions of Pharmacovigilance	0.938
Pharmacovigilance includes: (Components of Pharmacovigilance)	0.321
National pharmacovigilance program in Saudi Arabia is governed by: Saudi Food & Drug Authority (SFDA)	0.072
Definition of Adverse drug reaction	0.047*
ADRs which are independent can be treated by withdrawing the drug, reducing the dose and replacing the medications	0.555
Augmented drug reaction is: dose dependent, common in occurrence, rarely fatal.	0.606
Which one of the following is the "WHO online databases" for reporting ADRs	0.14
The health care professionals responsible for ADR reporting in a hospital	0.028*
*p<0.05	

Table 4 shows the correlation between the profession and responses of the healthcare professionals to knowledge-based questions on pharmacovigilance. It was statistically significant for two questions. First for the definition of adverse drug reaction and second for the question on responsibility of ADR reporting i.e., who can report an ADR?

Table 5 Correlation between the profession and responses of health care professionals to the attitude-based questions of pharmacovigilance

Questions	Pearson Chi-Square test (p-value)
Do you think reporting is a professional obligation to you?	0.491
ADR monitoring Centre should be in every hospital	0.068
Do you think reporting of ADRs is necessary?	0.0001***
Do you think Pharmacovigilance should be taught in detail to healthcare professionals?	0.024*
*p<0.05; ***p<0.0005	

Table 5 shows correlation between the profession and the responses of healthcare professionals to the attitude-based questions on pharmacovigilance. There was statistically significant correlation between the profession and responses of the healthcare professionals to the question of importance of ADRs and whether it should be taught in detail to them.

Table 6 Correlation between the profession and responses of health care professionals to the practice-based questions of pharmacovigilance

Questions	Pearson Chi-Square test (p-value)
Have you ever come across with an ADR	0.301
Have you come across any patient experiencing ADRs?	0.483

Have you ever attended an educational session about pharmacovigilance?	0.466
Have you read any article on prevention of ADRs?	0.204
Have you ever been trained on how to report ADRs	0.032*
Non-medical person can report ADR to a nearby Healthcare professional	0.341
Have you ever come across with an ADR and reported it?	0.539
* $p<0.05$	

Table 6 shows the correlation between the profession and responses of healthcare professionals to practice based questions on pharmacovigilance by Pearson's correlation test. It was statistically significant only for the question have you been ever trained on how to report the ADR.

DISCUSSION

The present study was conducted with the aim to investigate the knowledge, attitude, and practice of pharmacovigilance among the healthcare professionals and medical students in Majmaah region, KSA. Total of 148 participants took part in this questionnaire-based study, majority of which 89% were males and 11% females. The study participants included 42.56% of medical students, 16.89% pharmacists, 28.39% nurses and 12.16% doctors. Although we tried to include more number of doctors, pharmacists, and nurses in our study the rate of attrition was more in them.

Knowledge

The knowledge of pharmacovigilance like the definition of pharmacovigilance, ADR management and type of ADRs was more in doctors as they were more familiar with the practical aspects of these issues but still it was unsatisfactory as majority of them are still unaware of these facts. The knowledge of functional aspects of pharmacovigilance its components, reporting authority, definition of ADR and responsible personnel for reporting was more in pharmacists. This brings about a fact that pharmacists are more knowledgeable in these issues even compared to the doctors this may be due to their training which involves dealing with the drug related issues and importance given to it in their curriculum. The least knowledge of pharmacovigilance and ADRs was found in the nurses. Overall the knowledge and awareness regarding pharmacovigilance and ADRs was low ranging from 27% to 64.2%. The results of our study are in accordance with the studies by Al-Arefi, et al., in 2015 and Mohammed, et al., in 2015 [10,11].

Attitude

There was a consensus among the healthcare professionals including the medical students that reporting of the ADRs is necessary and it should be taught in detail to them. This denotes the positive attitude of healthcare professionals towards this aspect and can be utilized for behavioral modification to create a culture of reporting ADRs. Training regarding this should be provided to all health care professionals. Majority of the doctors had the attitude that reporting ADR is their professional obligation in comparison to the others as they are the ones who deal with these ADRs in the hospitals and manage them. Majority of the healthcare professionals believed that ADR monitoring center should be present in every hospital. This attitude was less in the medical students which may be due to lack of the recognition of importance of ADR reporting and less role in identification and management of these ADRs.

Practice

The incidence of ADRs (have you come across ADRs) was more in pharmacists as they may be more aware of the adverse drug reactions. As expected most doctors had encountered patients with ADRs as they are the first contact for the patients with these episodes. But the percentage of doctors reporting the ADRs was very low as was the case with other healthcare professionals overall reporting rate for ADRs was only 35.1% even though the percentage of professionals who encountered the ADRs were 52.7%. This shows the disparity in practice of reporting the ADRs. The reason for such behavior may be unawareness of the healthcare professionals to the practice of pharmacovigilance which correlates with the fact that less than 50% participants had read articles on prevention of ADRs or were trained in reporting in the ADRs.

Barriers to Reporting

The barriers to reporting the ADRs may be lack of training and awareness of this issue like where to report and whom to report and who to report as was shown by the poor knowledge of the healthcare professionals especially the nursing staff.

Busy schedule of the doctors, nurses and pharmacists may be one of the factors. This claim is also supplemented by the fact that in this study the attrition rate was high in them especially doctors who cited the reason of being busy. The other factors may include lack of incentives and insufficient clinical knowledge.

CONCLUSION

In conclusion the findings of this study point us towards an important aspect of medicine safety that is lack of knowledge about the adverse drug reactions and their reporting in doctors, nurses, pharmacists, and medical students. The lack of knowledge also reflects on their practice of not reporting the ADRs adequately. The National pharmacovigilance program is an important program for the safety of the patients as the consequences of ADRs are well known. The main pillars of strength for this program are the people who report the ADR. So, initiatives should be taken proactively to educate them about the nuisances of ADR reporting. The positive aspect is the attitude of healthcare professionals who are very receptive and feel the need for more training programs and awareness of this issue. So, our findings provide the healthcare policy makers and health authorities with a baseline reality that can be used for reinforcement plans and training initiatives for the success of the pharmacovigilance program and ultimately the benefit of the patients.

RECOMMENDATIONS

- Awareness campaigns for the adverse drug reactions and its reporting should be conducted.
- ADR monitoring center should be established in every hospital for facilitation of the ADR reporting.
- Training programs regarding Pharmacovigilance should be organized for the health care professionals
- The importance of ADR reporting and ADRs should be re-emphasized in the medical students.

DECLARATIONS

Conflict of Interest

The authors have disclosed no conflict of interest, financial or otherwise.

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