

HEALTHCARE PROFESSIONALS’ KNOWLEDGE, ATTITUDES AND PRACTICES TOWARDS PHARMACOVIGILANCE

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Abstract

Adverse drug reactions (ADRs) are known to be associated with morbidity and mortality and are one of the crucial problems associated with medicines. The aim of the Pharmacovigilance system is at sensitizing the healthcare professionals in spontaneous reporting of adverse drug reactions in order to improve patient care and safety. Active participation of the healthcare professionals is an important chain in achieving success of a pharmacovigilance program. Therefore, the objective of our study was to evaluate knowledge and attitude of the healthcare professionals toward pharmacovigilance and their practice regarding ADR reporting (KAP). About 45.3% of the participants gave correct response regarding the definition of pharmacovigilance. 42.1% of healthcare professionals were aware regarding the existence of a National Pharmacovigilance Program in Macedonia. A major difference was noted between adverse drug reaction experienced (51.6%) and ADR-reported (14.7%). Less percentage of participants had ever been trained on reporting ADRs. There is positive correlation between training of pharmacovigilance and reporting ADR by healthcare professional. Healthcare professionals should consider ADRs reporting an immense responsibility and professional obligation as a prerequisite of an effective national drug safety monitoring. Continuous education trainings are more than needed, so the healthcare professionals in Tetovo can become powerful participants of ADR reporting system.

Keywords: Pharmacovigilance; Adverse drug reactions; Healthcare professionals; Self-administered questionnaire.

INTRODUCTION

Pharmacovigilance is the pharmacological science relating to the collection, detection, assessment, monitoring and prevention of adverse effects or any other drug-related problem, mainly long term or short term side effects of pharmaceutical products (World Health Organization, 2002). Adverse drug reactions (ADRs) as the most significant morbidity and mortality reason are defined as a noxious, unintended and undesirable effect that occurs as a result of drug treatment at doses normally used in humans for diagnosis, prophylaxis, and treatment (Ahmad A, Patel I, Balkrishnan R, Mohanta GP, Manna PK, 2013).

Drug safety and pharmacovigilance remains a dynamic clinical and scientific discipline. The aim and scope of pharmacovigilance is broad and includes multiple components such as medication errors, counterfeit and unauthorized medicines, lack of efficacy, drug interactions, and rational prescription of medicines (World Health Organization 2015). The Uppsala Monitoring Centre (UMC, WHO), Sweden is maintaining the international database of ADR reports received from several national centers. Although, R. of North Macedonia is participating in the program, its contribution to UMC database is not satisfactory (Kaur M, Kosey S, Kumar R, 2015).

Healthcare professionals are known to be one of the crucial participants for the success of pharmacovigilance system. Despite global concerns against medication safety, there is a lack of awareness and knowledge of pharmacovigilance and ADR reporting among healthcare professionals yet (Najafi S 2018). The knowledge, attitude, and practice (KAP) is the best tool

to assess ADR reporting among healthcare professionals and their perspective towards Pharmacovigilance and patient's safety (Ganesan S, Vikneswaran G, Reddy KC, Subrahmanyam DK, Adithan C, 2016), (Desai CK, Iyer G, Panchal J, Shah S, Dikshit RK, 2011), (Gupta SK, Nayak RP, Shivaranjani R, Vidyarthi SK, 2015).

In this context, the objective of our study was to evaluate knowledge and attitude of the healthcare professionals toward pharmacovigilance and their practice regarding ADR reporting (KAP).

MATERIAL AND METHODS

Study design

This is a cross-sectional questionnaire based study, conducted from September to October 2018, in Tetova, an urban city in the north-western part of the Republic of North Macedonia. The health care professionals i.e., doctors, pharmacists and nurses were included in the study. Verbal consent was obtained from all participants enrolled in the study before administering the questionnaire. No personal identifiers were included in the form.

Questionnaire development and grading

The questionnaire was adapted taking into consideration the previously conducted studies. KAP questionnaire was designed to capture the demographic data of the healthcare professionals, their knowledge of pharmacovigilance, attitudes towards pharmacovigilance and practice regarding ADRs reporting.

In the first part of the questionnaire, demographic data of the healthcare professionals such as sex, age and profession was noted. The knowledge part consisted of 5 questions, attitudes part 6 questions and practice part contained five questions. In the attitude part a score of 4 to 6 was considered as satisfactory, score of 2-4 was considered as unsatisfactory and score of less than 2 was considered as poor.

The questionnaire was administered by the investigator personally to the community pharmacist to obtain the response.

Statistical analysis

The data obtained were analyzed using appropriate statistical analysis through SPSS statistical software.

The frequency and percentages of right answers for knowledge were calculated and the questions of attitude and practice were evaluated. Pearson's correlation test was used to evaluate the correlation between training of pharmacovigilance and reporting adverse drug reaction.

RESULTS

Among 120 healthcare professionals who were offered to participate in the study, 95 of them completely filled questionnaire and were included for analysis. The response rate was around 79.2%.

Out of 95 healthcare professionals, 57 (60%) were female, and 38 (40%) were male. Majority of them (41.1%) were in the age group of 30-40 years. Pharmacists were 38 (40%), doctors 32 (33.7%) and nurses were 25 (26.3%) (Table 1).

Table 1. Demographic details of the healthcare professionals

Characteristics	Percentage
<i>Gender</i>	
Male	60
Female	40
<i>Age distribution</i>	
19-30	27.4
30-40	41.1
>40	31.5
<i>Health care professionals</i>	
Doctors	33.7
Pharmacists	40.0
Nurses	26.3

Knowledge of healthcare professionals on pharmacovigilance

About 45.3% of the participants gave correct response regarding the definition of pharmacovigilance. Only 9.5% healthcare professional were aware that the most important purpose of pharmacovigilance is to identify safety of the drug. 42.1% of healthcare professionals were aware regarding the existence of a National Pharmacovigilance Program in North Macedonia. 69.5% of healthcare professionals were aware that MALMED is the regulatory body responsible for monitoring of ADR's in North Macedonia. Only 23.2% were aware that International Center for ADR monitoring is located in Sweden (Table 2).

Table.2 Knowledge related questions and percentage of correct and incorrect responses

	Correct	Incorrect
Define Pharmacovigilance?	45.3	54.7
The important purpose of Pharmacovigilance is?	9.5	90.5
Do you know about the International Pharmacovigilance Program?	42.1	57.9
In Republic of North Macedonia which Regulatory body is responsible for monitoring of ADR's?	69.5	30.5
The international centre for adverse drug reaction monitoring is located in?	23.2	76.8

Attitude of healthcare professionals towards pharmacovigilance

Out of the total respondents, ADR reporting as a professional obligation was positive for 76.8%, 97.8% of healthcare professionals stated that reporting of ADR is necessary and 65.3% were aware that all healthcare professionals are responsible for reporting ADRs. 92.6% agreed

that pharmacovigilance should be taught in detail to healthcare professionals and 66.3% of respondents have read articles on prevention of ADRs. Only 29.5% healthcare professional agreed that ADR monitoring center should be established in every hospital (Table 3).

Table 3. Health care professionals' response towards attitude-related questions

Attitude related questions	Correct response (%)
Do you think ADR reporting is professional obligation for you?	76.8 (Yes)
The healthcare professionals responsible for reporting ADRs in a hospital is/are	65.3
Do you think reporting of adverse drug reaction is necessary?	97.8 (Yes)
Do you think Pharmacovigilance should be taught in detail to healthcare professionals?	92.6 (Yes)
Have you anytime read any article on prevention of adverse drug reactions?	66.3 (Yes)
What is your opinion about establishing ADR monitoring centre in every hospital?	29.5 (Yes)

Figure 1 shows the mean scores of attitude towards pharmacovigilance among healthcare professionals. It shows that mean scores of doctors and pharmacists is much higher than nurses. The mean attitude score of pharmacist is 4.32 followed by doctors 4.18 and fall under satisfactory range while that of nurses falls under unsatisfactory range with score of 2.3 (Figure 1).

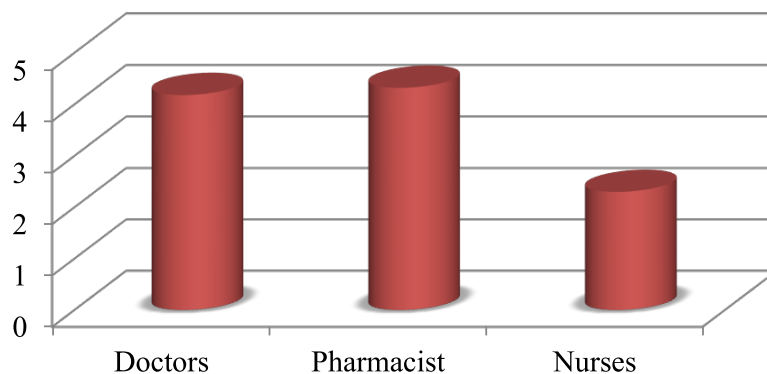


Figure 1. Mean attitude scores of healthcare professionals

Practice regarding ADRs reporting

Among the respondents, a major difference was noted between adverse drug reaction experienced in their day to day clinical practice (51.6%) and ADR-reported (14.7%). Less percentage of participants (21.1%) have been trained on how to report a ADR and only 42.1% have seen the ADR reporting form (Table 4).

Table 4. Practice - related questions and percentage of response

Practice-related questions	Correct response (%)
Have you ever experienced adverse drug reactions in your patient during your professional practice?	Yes (51.6)
Have you ever reported ADR to the Pharmacovigilance centre?	(Yes) 14.7
Have you ever seen the ADR reporting form?	(Yes) 42.1
Have you ever been trained on how to report Adverse Drug Reaction (ADR)?	(Yes) 21.1
Are you aware of any drug that has been banned due to ADR? (%)	(Yes) 76.8

The correlation between the training of pharmacovigilance and reporting ADR was analyzed by using Pearson's correlation coefficient. There is a positive correlation between training of pharmacovigilance and reporting ADR by healthcare professional. ($r = 0.414$, $n = 95$, $P < 0.001$) (Table 5).

Table 5. Correlation between training of pharmacovigilance and reporting ADR by healthcare professional

		Have you ever reported ADR to the Pharmacovigilance centre?	Have you ever been trained on how to report Adverse Drug Reaction (ADR)?
Have you ever been trained on how to report Adverse Drug Reaction (ADR)?	<i>Pearson correlation</i>	1	0.414**
	<i>Sig. (two-tailed)</i>		0.001
	<i>N</i>	95	95
Have you ever reported ADR to the Pharmacovigilance centre?	<i>Pearson correlation</i>	0.414**	1
	<i>Sig. (two-tailed)</i>	0.001	
	<i>N</i>	95	95

DISCUSSION

The present study is a survey based which was carried out to assess the knowledge, attitude and practice of pharmacovigilance and ADR reporting among healthcare professionals in Tetova, Republic of North Macedonia.

Knowledge regarding pharmacovigilance is very important when it comes to reporting, evaluating and prevention of drug adverse reactions. It was previously shown that knowledge and attitudes exerted a strong influence on ADR reporting (Herdeiro *et al.* 2006).

It is as well very important for healthcare professionals to possess great knowledge about ADR and the procedure of reporting ADR. The results showed that healthcare professionals do not have significant knowledge which is in correspondence with different studies conducted for

the same aim. Healthcare professionals' knowledge was followed based on some important questions. 45.3 % of the respondents gave correct response regarding the definition of Pharmacovigilance which is not in accordance with the 90.5% of them who do not know its important purpose. 69.5 % of the respondents were aware of the regulatory body responsible for monitoring ADR's in North Macedonia even though 76.8% do not know the location of the international centre for adverse drug reaction monitoring. This result is very crucial and indicates that there is much more need to be done to educate healthcare professionals on pharmacovigilance. The results of the present study are slightly lower with regard to knowledge when compared to a similar study done by Srinivasan *et al.* (2017) and Tadvil *et al.* (2018). Lack of knowledge regarding ADR reporting among physicians and pharmacists is also reported in Saudi Arabia (Abdel-Latif, 2015).

The survey denotes the positive attitude of healthcare professionals towards the necessity of ADR reporting, which in fact is an important indicator for the proper actions that should be taken to improve participation of healthcare professionals in ADR reporting.

About 76.8% of respondents agreed that ADR reporting is their professional obligation which is comparable to a similar study done by Tadvil *et al.* (2018) A study carried out in Karachi, Pakistan shows 64% respondents believed physicians and 31.2% considered pharmacists are the most appropriate persons to report ADR (Iffat W *et al.*, 2014). But in the present study, a different trend was observed as 6.3% stated that doctors are qualified to report ADR, 28.4% believed that pharmacists, while 65.3% consider that all mentioned healthcare professionals (i.e doctors, pharmacist and nurses) are responsible for reporting ADRs.

A total of 92.6 % of the participants were of the view that pharmacovigilance should be taught in detail to healthcare professionals which coincides with study of Srinivasan *et al.* (2017) and Tadvil *et al.* (2018). In other hand only 29% of respondents believed that ADR monitoring center should be established in every hospital, which is far less from the percentages reported in other studies.

Although mean attitude scores among doctors and pharmacists were higher than nurses, serious measures should be taken to educate healthcare professionals about pharmacovigilance.

The ADR reporting practice among healthcare professionals was not satisfactory as well. In this study there was huge gap between the ADR experienced (51.6%) and ADR reported (14.7%) by healthcare professional. These results are in contrast with a study conducted in Sweden where 60% of healthcare professionals report ADR to appropriate authority. (Rishi *et al.*, 2012, Mulatu and Worku, 2014).

In developed countries ADR reporting rate is high and the main reason behind this is that the ADR monitoring system is well established.

Majority of respondent (78.9%) stated that they have never been trained for reporting ADR. Similar results were found in a study conducted in Quetta, Pakistan where 89% of healthcare professionals declared that they have never been trained on ADR reporting (Anwar and Haq, 2017).

Similarly, a study in UAE reveals that 94.5% of physicians did not receive any training regarding ADR reporting (John *et al.*, 2012). This parameter is an important indicator for urgent need efforts on improving ADR reporting system in North Macedonia.

Our study denotes the fact that there is positive correlation between training of pharmacovigilance and reporting ADR by healthcare professional which indicates the importance of academic interference in monitoring and reporting ADRs. Study by Rajesh *et al.* (2011) confirmed that educational interventions lead to an increased awareness about ADR reporting.

Educational training related to pharmacovigilance should be conducted where training to healthcare professionals should be given regarding the purpose and importance of pharmacovigilance and where and how to report ADR as well.

CONCLUSION

Healthcare professionals as a crucial part of the pharmacovigilance system, should be well educated about the procedure reporting adverse event and its importance and as well considerable knowledge for higher and successful reporting of the adverse drug reactions. So, our findings emerge the need for continuous educational trainings such as updates on the ADR reporting form, reporting centers, the importance of reporting for success of the pharmacovigilance program and the patients safety as well. The positive aspect of this study is the positive attitude of healthcare professionals who feel the need for more training programs and awareness of this issue.

Further studies are recommended at a national level to determine ADR reporting practice and as well factors and barriers in reporting ADR.

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