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PHARMACISTS' KNOWLEDGE, ATTITUDE AND PRACTICE ABOUT ADVERSE DRUG REACTION IN BASRA/IRAQ

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ABSTRACT: Pharmacovigilance can be helpful in defending consumers from harmful effects of medicines. Pharmacists should consider Adverse Drug Reaction (ADR) reporting as their professional obligation and should be aware of the existing pharmacovigilance mechanisms in their countries. **Purpose:** The present study evaluated the knowledge, attitude and practices (KAP) of the pharmacists towards ADRs and pharmacovigilance in Basra Hospitals. **Methods:** A cross-sectional analytical study was carried out in the province of Basra. All the pharmacists present in the Basra province during the study period were enrolled in the study and the convenience sampling technique was utilized for analysis. Hence, 530 pharmacists took part in the study. This questionnaire was tested and made error-free prior to using. This questionnaire contained 5 knowledge-based questions, 5-attitude related questions and tow questions which were related to the practices used towards the ADRs. **Results:** The response rate was 24.9 %.The results of our study clearly point out that in spite of the pharmacists positive attitude there was a lack of appropriate knowledge and practice to implement ADRs reporting successfully. The results emphasized the critical need for interventions to support ADRs reporting activity and to maintain Pharmacist's positive attitude. **Conclusion:** Our findings suggested that the need for positive evidence based on educational and managerial interventions regularly to improve ADR reporting. It would be more beneficial, if the Ministry of higher education would suggest some more measures to review and perhaps improve pharmacy colleges' curricula to guarantee the incorporation of PV and ADRs reporting system conception.

INTRODUCTION: Drug safety monitoring has greatly improved in recent years, specifically following the thalidomide tragedy which took place during the 1960s. [1] One of the most important areas in the field of Pharmacovigilance (PV) are the studies involving the post-marketing safety issues regarding the Adverse Drug Reactions (ADRs).

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According to WHO, PV can be defined as the science and the activities with respect to the assessment, detection, understanding and the prevention of the harmful results or any adverse drug-related issues. [2] The ADR reports are the main source of the data available in PV. [3] Also, the ADRs are a very big cause of mortality and morbidity, globally. [4] Additionally, the ADRs would cause an economic burden and increase the cost of basic healthcare, as they could increase the cost of hospitalisation. [5] WHO defines ADR as any type of response caused by a drug, that is unintentional, noxious and takes place at the drug doses which are used for diagnosing, prophylaxis,

or treatment of a disease or due to the medications for the physiological functions. [3]

The Iraqi Pharmacovigilance Centre (IPhvC) was established in MOH in early 2010, and it helped Iraq obtain a permanent membership in the worldwide drug monitoring program and Iraq gained a 102nd position amongst all the members. [6] Several studies have focused on the relation between the knowledge, attitude and practice (KAP) of the ADR amongst the pharmacists.[3, 4] Till date, no reports have been published in Iraq with respect to the KAP attitude of the pharmacists towards the PV system and the ADR studies. In this study, we have selected some pharmacists, representing the whole study population. The study aims to find out the KAP of the pharmacists regarding the ADRs.

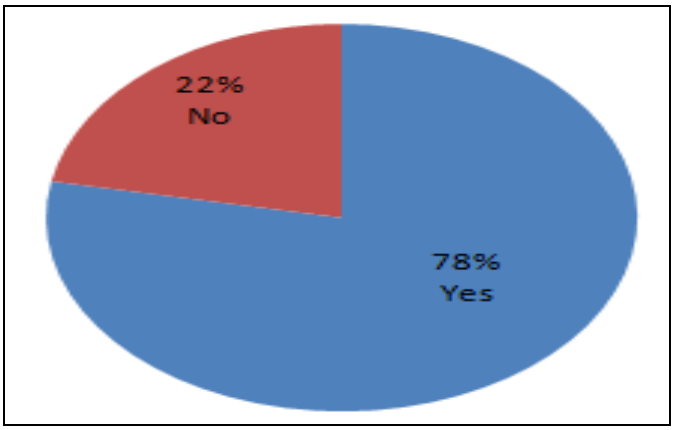
Method: A cross-sectional analytical study was carried out in the province of Basra, during Feb – July 2015. All the pharmacists present in the Basra province during the study period were enrolled in the study and the convenience sampling technique was utilized for analysis. Hence, 530 pharmacists took part in the study.

The KAP of the pharmacists was determined based on a well-structured, self-administered and validated questionnaire. This questionnaire was tested and made error-free prior to using. [7-9] This questionnaire contained 5 knowledge-based questions, 5-attitude related questions and tow questions which were related to the practices used towards the ADRs. The pharmacists were interviewed and data was collected. The questionnaire had to be answered within 30 minutes before being analyzed.

RESULTS: The total 132 pharmacist provided their response. The demographic details of the respondents are tabulated in (**Table 1**). Most of the participants of the survey were familiar with the terms of ADR and Pharmacovigilance, i.e., 78% (103), and 66.7% (88) respectively (**Fig. 1-2**), where around 75% (99) of the participants were unaware of the "ADR reporting programs in Iraq". Additionally, 8.3% (11) participants were aware of the mechanism of making a report using ADR, while 16.7% (22) participants had an idea about the PV centre and the program in Iraq. There was a statistically significant difference in response to this statement according to the age (p = 0.03). A high proportion (n = 47, 42.7%) of the respondents aged 31-40 said (No) to this statement compared to the other age groups. However, no statistical difference was found with the other demographic characteristics (**Table 2**).

TABLE 1: PHARMACISTS' DEMOGRAPHIC CHARACTERISTICS

Variable	Frequency (%)
Age	
24-30	29 (22)
31-40	59 (44.7)
>41	44 (33.3)
Gender	
Male	54 (40.9)
Female	78 (59.1)
Years of experience	
1-10 years	38 (28.8)
11-20 years	60 (45.5)
More than 21 years	34 (25.8)
Qualification	
B.Sc. Pharm.	110 (83.3)
Diploma	1(8)
M.Sc. Pharm.	14(10.6)
PhD	7(5.3)



FIG, 1: ARE YOU FAMILIAR WITH THE TERMS ADRS

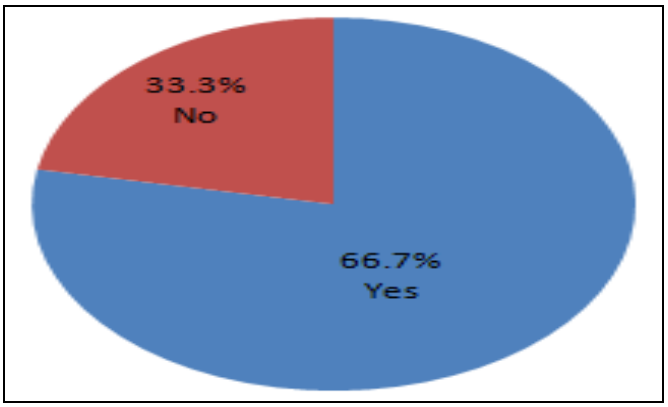


FIG. 2: ARE YOU FAMILIAR WITH THE TERMS PHARMACOVIGILANCE

TABLE 2: RESPONSES TO KNOWLEDGE RELATED QUESTIONS

Items in questionnaire	Responses *		P Value **			
	Yes N (%)	No N (%)	Age	Gender	Qualification	Year of practice
Are you aware of any ADRs reporting program in Iraq	33 (25)	99 (75)	0.06	0.31	0.23	0.21
Do you know how to make report of ADR	11 (8.3)	121 (91.7)	0.11	0.10	0.12	0.06
Do you have any idea regarding National Pharmacovigilance Centre in Iraq	22 (16.7)	110 (83.3)	0.03*	0.06	0.90	0.21

Though the survey revealed that the pharmacists had a poor knowledge with regards to the national PV centre and the programs, they still possessed a good attitude towards ADR. Around 84.1% (111) participants agreed that "reporting the ADR was a part of the pharmacist's professionalism". While 84.9% (112) believed that observing drug safety was very important. Also, 75% (99) of the participants agreed that before an ADR reporting, a physician must be consulted. 25% (33) respondents did not agree with the statement that the "ADRs reporting must be made compulsory for all pharmacists". Meanwhile, 50.8% (67) of the participants agreed with the fact that the "ADRs report related to the OTC drugs which are provided by the pharmacy is essential". There were no statistically significant differences noted between the responses to these statements and the demographic measures (**Table 3**). However, all the respondents agreed to the fact that the ADRs, which lead to serious problems, are very important events which needed to be reported (**Fig. 3**).

TABLE 3: RESPONSES TO ATTITUDE RELATED QUESTIONS

Items in questionnaire	Responses		P Value			
	Yes No.(%)	No No.(%)	Age	Gender	Qualification	Year of practice
1-Reporting ADRs are part of the professional role of a pharmacist.	111(84.1)	21(15.9)	0.81	0.60	0.06	0.91
2-I believe that the science of monitoring drug safety (pharmacovigilance) is important	112 (84.9)	20(15.1)	0.30	0.7	0.10	0.60
3-Consulting the physician is important before reporting an ADR	99 (75)	33(25)	0.06	0.10	0.1	0.2
4-ADRs reporting should be compulsory	99 (75)	33(25)	0.21	0.10	0.20	0.11
5-I don't report ADRs of OTC drugs supplied by my pharmacy	65 (49.2)	67 (50.8)	0.06	0.06	0.07	0.06

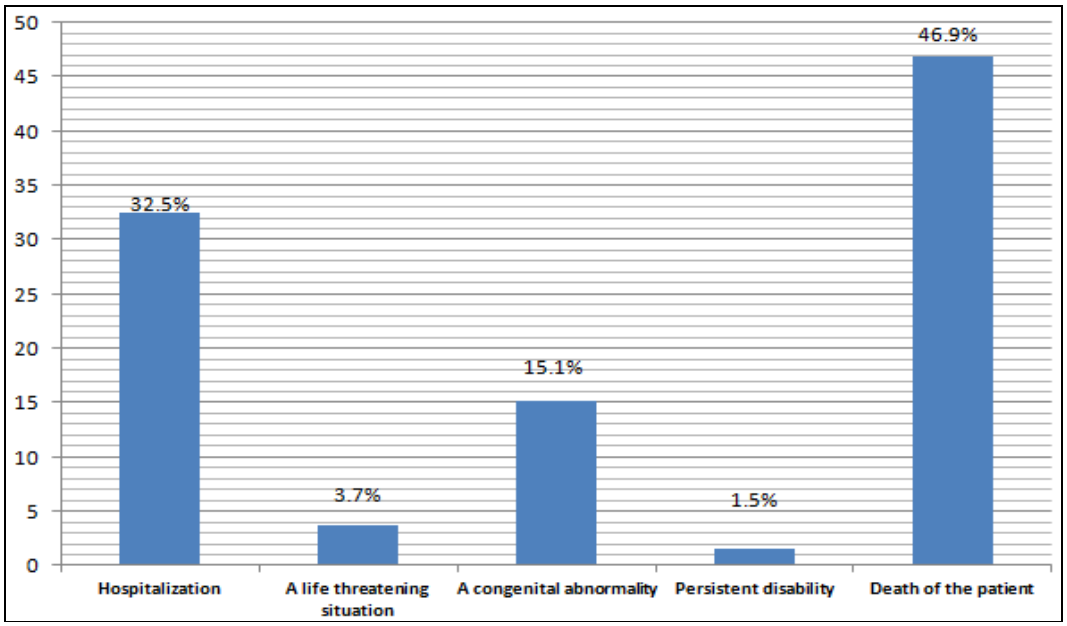


FIG. 3: REPORT ADRS LEADING TO SERIOUS PROBLEM

Most of the participants of the survey, i.e., 93.9% (124), did not send an ADR report (**Fig. 3**). There were no a statistically significant difference in response to this statement according to the age (p = 0.56), gender (p= 0.84), Years of experience (p=0.61) and qualification (p=0.1). There are many important obstacles which prevent the pharmacists from reporting an ADRs report, some of which are highlighted in **Fig. 4**.

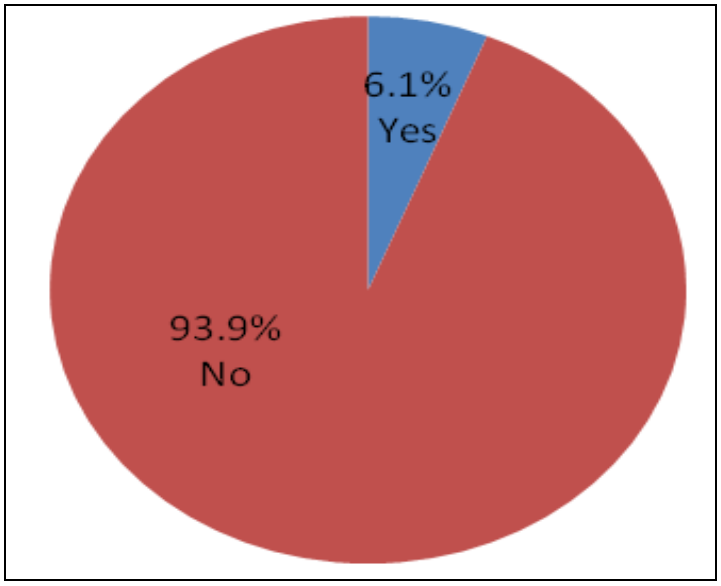


FIG. 3: HAVE YOU EVER SENT ADR REPORT

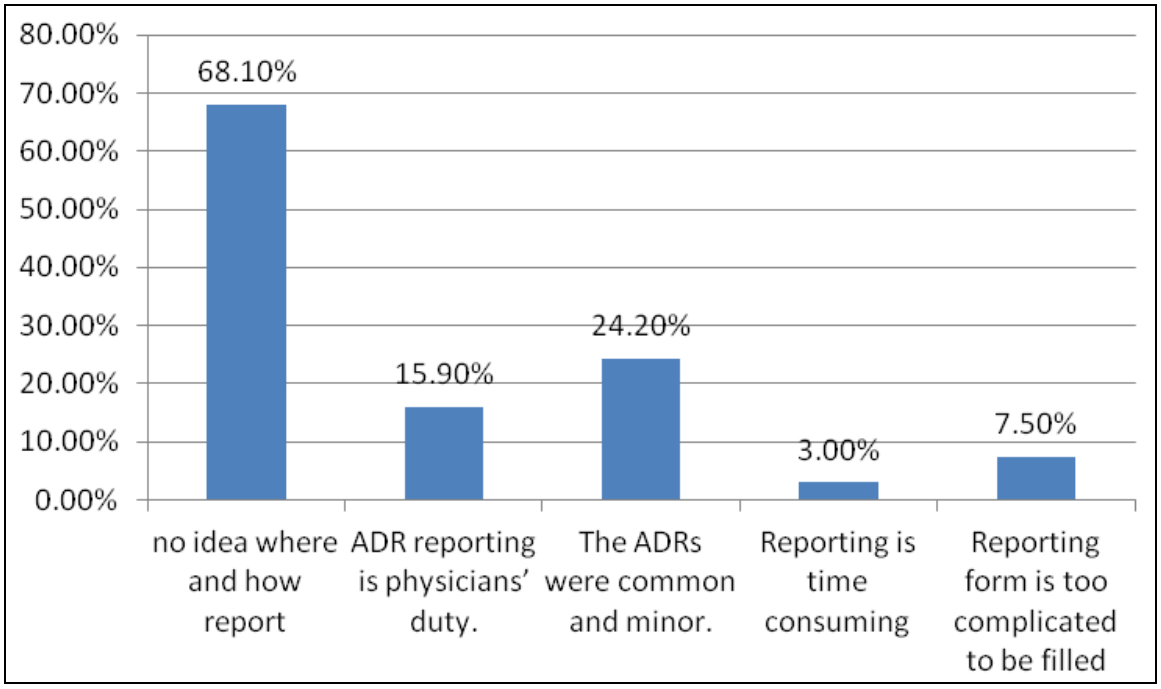


FIG. 4: BARRIERS WHICH PREVENT PHARMACIST TO REPORT ADRs

DISCUSSION: The pharmacovigilance programme has been started in several nations, including Iraq, for recognising ADRs, which form a very serious health-related issue. Reporting of the ADRs forms the major database for the program which helps to improve the drug usage pattern. The very serious issue under the program is the ADR under-reporting. To the best of our knowledge, this study is the first of its kind, conducted in Iraq/Basra region. The response rate in the study was around 24.9%, which indicated a lack of awareness and a poor knowledge amongst the participants about the PV and the ADRs reports in Iraq.

The results of our study indicated that the participating pharmacists were quite knowledgeable towards the PV and the ADR terminology, which was in direct contrast to the study which was carried out in Turkey that indicated the lack of knowledge amongst the community pharmacists regarding the terms.[10] However, our study indicated that there was a poor knowledge amongst the participants regarding the ADR reporting procedure and the PV centre activities, which is similar to the data observed in the studies carried out in Gujarat, Hong Kong, Iran, Malaysia, and Saudi Arabia.[11-14, 4] However, only 7% of the UK pharmacists were unaware of the ADR reporting.[15] These results indicate that there is a lack of adequate programme announcement to the pharmacists, which indirectly highlights the importance of developing relevant strategies which improve the knowledge regarding the availability of PV centre in Iraq.

All the participants of this study displayed very positive reactions towards the ADRs report. Similar results were also observed in other studies conducted in the UK. [15, 16] However, in New Zealand, a study reported that the participants displayed a negative reaction for ADR reporting.[17] Our study demonstrated a very strong reaction, wherein all the pharmacists (100%) considered ADR reporting to be their very essential role. Similar results were seen in the studies carried out in UAE and Malaysia. [13, 7]

Around 75% of the participants in the study agreed with the fact that the ADR reporting must be made mandatory for all the pharmacists, and this was also observed in the study carried out in KSA.[18] However, one disappointing observation noted in this study was the fact that three-fourths of the participating pharmacists thought that consulting a physician would necessary before ADR reporting. But these results were also noted in the study conducted in Netherlands and KSA.[18-19] All these observations indicate that the pharmacists lack confidence and fear the subsequent legal consequences which could arise after an ADR reporting. However, these facts must not be considered in the programme, as they could interfere with reporting and result in the pharmacist opinion being dependent on the physicians. [20] Our results also noted that more than 70% of the pharmacists did not report ADR about the OTC drugs, which were provided by them. Similar results were noted by the study carried out in UAE, wherein 97.3% pharmacists did not agree to report the ADRs resulting due to OTC. However, opposite results were noted in the study in KSA, wherein a majority of pharmacists were ready to report the ADRs due to OTC.[7] These findings suggest that there is an urgent need to educate all the pharmacists regarding the ADR reporting guidelines and also we need to persuade the pharmacists to report the use of drugs and herbal products. The ADR reporting was noted to be low, wherein a mere 6.1% of the participants provided ADR reports to the health ministry.

Other studies have revealed that ADR reporting in other countries varied between 3%-14.7%.[15] The important parameter resulting in these low values could be the fact that the pharmacists (91.7%) did not know the manner and the place to report, which was similar to the results noted in a Turkish study.[10] Therefore, a proper and intensive involvement of the pharmacists in the training programs in the field of pharmacovigilance and unprompted reporting could result in a decrease in under-reporting.

CONCLUSION: In the developing countries, patients prefer to contact the pharmacists first in case of a suspected reaction to the drugs. Therefore the PV center should make sure of the availability of the reporting forms by distributing them to the pharmacies, drug stores, hospitals and any other health providing system. The results of the present study demonstrate that the majority of the pharmacists in Basra have insufficient knowledge about pharmacovigilance practice. The Ministry of higher education should find measures to review and improve pharmacy colleges' curricula to guarantee the incorporation of PV and ADRs reporting system conception

CONFLICTS OF INTEREST: None

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