

## **Reporting Adverse Drug Reactions: Evaluation of Knowledge, Attitude and Practice among Community Pharmacists in UAE**

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**ABSTRACT :** In United Arab Emirates (UAE), the pharmacovigilance (PV) program is in the stage of initiation therefore the success of such a program depends upon the participation of the health care professionals. No study has been found regarding the role of the community pharmacist as a health care provider in monitoring drug safety after marketing. This study aimed to evaluate the knowledge, attitudes and practice (KAP) toward adverse drug reactions (ADRs) reporting among community pharmacists (CPs) in Ajman and Sharjah, UAE. Evaluating the baseline KAP of the CPs regarding ADRs reporting can be useful in providing information for the progress of a PV program in UAE. An interview questionnaire was delivered to 300 CPs in Ajman and Sharjah cities. Statistical Package for the Social Sciences (SPSS) version 20 was used for data analysis. Only 4.9% of respondents had good ADRs reporting knowledge, while the majority of pharmacists 93.7% had a positive attitude towards ADRs reporting. Forty four percent of the pharmacists were not alert about ADRs reporting program in UAE. Only 3.6 % of the enrolled pharmacists submitted ADRs report and only 11.2% had good practice score. The results of our study clearly point out that in spite of the community 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 CPs positive attitude.

**KEYWORDS -** Adverse Drug Reaction (ADRs), Attitude, Community Pharmacists, Knowledge, Pharmacovigilance, Practice, Reporting.

### **I. INTRODUCTION**

The Adverse drug reactions (ADRs) are a cause of morbidity and mortality [1-3]. Moreover, ADRs are one of the causing factors for hospital admissions [4-6]. It had been found that the incidence of ADRs induced hospital admissions is 6.7% of all medical admissions [7]. Huge economic loss have been associated with ADRs [7-9]. Not all ADRs can be recognized from early safety studies done by the manufacturer, so it is very important to monitor ADRs after marketing [3, 10]. The tragedy of the Thalidomide disaster has encouraged many countries to establish Pharmacovigilance (PV) systems for detecting ADRs of drugs available in the market [11].

Spontaneous reporting systems are considered the main mechanism of PV system to gather information about ADRs after the drug released into the market [12]. Under reporting of ADRs is a major obstacle for the progress of PV programs [13]. Researches from different countries all over the world found a strong association between ADRs reporting and knowledge, attitude and practice (KAP) of the health care professional [3, 14-18]. Thus improving the KAP of health care professional is essential for establishing and improving PV program in any country [19, 20]. Community pharmacists (CPs) are important source of ADRs reporting because of the fact that they are the first to be contacted by patients in most ADRs cases [2].

However, no study has been found regarding the role of CPs as ADRs reporters in UAE. Even though, the pharmacists has an immense responsibility in strengthening PV system [2, 21]. Knowledge of pharmacists on ADRs reporting was found to be inconsistent. Several studies had shown low level of knowledge [22] while others attributed a good knowledge level [23]. Several studies had shown that health care professionals were having the needed information on how to find out ADRs but they don't know where to send ADRs reports [ 24-26]. Attitudes on ADRs reporting were not rated in the same level among health care professionals. Some studies revealed positive attitudes [25, 26] while other studies reported negative attitudes [22, 27].

**STUDY OBJECTIVES:** To determine the knowledge, attitudes and practice and the association between knowledge, attitudes and practice among UAE CPs toward ADRs reporting.

## **II. MATERIALS AND METHODS**

A cross- sectional study was conducted using multistage sampling method, convenience and simple random sampling were applied respectively. The KAP questionnaire was designed based on the parameters to be evaluated as part of the study and by referring to previous literature [16, 19]. Modifications were done to make it convenient for UAE CPs. The developed questionnaire was designed to be interview-administrated. The questionnaire compromised of 4 parts: social- demographic, knowledge, attitude and practice. The minimum sample size was calculated using Raosoft sample size calculator (218) [28]. The final chosen sample size was 300 to overcome non response and to avoid decreased sample size than minimum.

Face validity was done by university lecturers and experts. Ten pharmacists enrolled in a pilot study to examine the survey reliability, determine the time needed for data collection and to revise and finalize the questionnaire. The registered licensed Cps working in Ajman and Sharjah in 2013, males and females who were willing to participate were included in the study. Community pharmacists who were not willing to participate, on leave during the study and unlicensed or unregistered were excluded from the study.

One pharmacist was selected from each pharmacy. The selection was done at the same time of the visit by inviting the available licensed community pharmacist. Pharmacists who were willing to be enrolled in this study were asked to sign informed consent forms. No attempt was made to prompt the respondents by suggesting answers directly.

**DATA ANALYSIS:** All questions were coded and then imported to SPSS version 20 for analysis. Descriptive analysis was used to analyze the socio-demographic data. A correlation analysis was performed to test association. P value of less than 0.05 was considered significant.

## **III. RESULTS**

The response rate was 74.3% in which the total number of usable data was 223. The socio-demographic characteristic of the enrolled pharmacists are listed in Table (1).

**Table 1: Social demographic data of the respondents**

<b>Variables</b>	<b>Sub groups</b>	<b>Frequency</b>	<b>Percentage</b>
Age	22-30	83	37.2
	31-40	80	35.9
	41-50	43	19.3
	51 or over	17	7.6
Nationality	South Eastern Asia	88	39.5
	Arab	103	46.2
	Others	32	14.3
Graduation year from pharmacy college	<5 years	61	27.4
	5-10 years	66	29.6
	>10 years	96	43.0
Post graduate certificate	Yes	24	10.8
	No	199	89.2
Type of postgraduate certificate	Diploma	2	0.9
	Master	21	9.4
	PhD	2	0.9
Experience years	<5 years	65	29.1
	5-10	66	29.6
	>10 years	92	41.3
Number of prescription dispensed per day	<20	90	40.4
	21-30	54	24.2
	>10	79	35.4
Number of patient served per day	<30	21	9.4
	31-50	81	36.3
	>50	121	54.3
Time spent with patient	<5 minutes	42	18.8
	5-10 minutes	102	45.7
	>10 minutes	17	7.6

Eleven (4.9%) of the respondents had a good knowledge score while 212 (95.1%) had poor knowledge score (Table 2).

**Table 2: Responses to the knowledge related questions**

Good Knowledge		Frequency	Percentage
Questions			
1. Are you aware of any ADRs reporting program in United Arab Emirates (UAE)?		124	55.9
2. Do you consider ADRs reporting as a natural task for a pharmacist?		176	78.9
3. Is it possible for a community pharmacist in UAE to report ADRs to the Ministry of Health (MOH)?		118	52.9
4. Are you familiar with the term Pharmacovigilance?		59	26.5
5. If yes, please define the term Pharmacovigilance?		44	19.7
6. What do you understand by the term ADR?		0.0	0.0
7. Do you know the difference between Adverse Drug Reaction type 1 and Adverse Drug Reaction type 2?		28	12.6
8. If yes, please define?		15	6.7
9. Do you know how to report an ADR?		37	16.6
10. Do you know that only proven ADR for an old drug should be reported to MOH?		21.1	47
11. There is no need to report the reactions related to Over the Counter products or herbal products in UAE.		115	51.6
13. Do you know in which country the international center for ADR monitoring is located?		21	9.4
14. If Yes, specify.		6	2.7
15. Do you know the name of the scale used to establish the causality of ADR?		5	2.2
16. If yes, please specify.		1	0.4
17. Do you know the name of the scale used to establish severity of ADR?		2	0.9
18. If yes, please specify.		0.0	0.0
19. Which one of the following drugs is known to cause fatal anaphylaxis reaction?		162	72.6
20. Type I hypersensitivity reactions can be prevented by which of the followings?		194	87.0

Ninety three percent (209) had positive attitude score while 6.3% (14) had negative attitude score. For positive attitude items, where pharmacists should have, the percentage ranged from 84.8% to 95.1%. While for the negative attitude items, where pharmacists should not have, the percentage ranged from 1.3% to 39.9% (Table 3).

**Table 3: Responses to the attitude related questions**

Positive attitude <sup>a</sup>		Frequency	Percentage
Questions			
1. Community pharmacist should be involved in ADRs reporting process. <sup>p</sup>		193	86.5
2. It is important for community pharmacist to attend training programs in pharmacovigilance. <sup>p</sup>		192	86.1
3. Reporting ADRs is part of the professional role of a pharmacist. <sup>p</sup>		199	89.2
4. I believe that the monitoring drug safety is important. <sup>p</sup>		208	93.3
5. It should be confirmed that ADR is related to the drug before reporting. <sup>n</sup>		6	2.7
6. It is not necessary to report ADRs of OTC products supplied by my pharmacy. <sup>n</sup>		89	39.9
7. It is important to report ADRs leading to hospitalization. <sup>p</sup>		205	91.9
8. It is important to report ADRs leading to a life threatening situations. <sup>p</sup>		212	95.1
9. It is important to report ADRs leading to congenital abnormality. <sup>p</sup>		209	93.7
10. It is important to report ADRs leading to persistent disability or incapacity. <sup>p</sup>		204	91.5
11. It is important to report ADRs leading to patients death. <sup>p</sup>		210	94.2
12. It is important to report ADRs in order to answer the questions that may arise in my practice. <sup>n</sup>		3	1.3
13. Reporting of ADRs is important to show patients that their concerns are taken seriously. <sup>p</sup>		204	91.5
14. Reporting ADRs is part of pharmaceutical care process. <sup>p</sup>		206	92.4
15. Consulting the physician is important before reporting an ADR. <sup>n</sup>		7	3.1
16. It is important to discuss ADRs with pharmacologist and/or university lecturer. <sup>p</sup>		189	84.8

<sup>a</sup> : Proportion positive attitude who answer agree for attitude that they should have and disagree for attitude that they should not have.  
<sup>p</sup>: positive attitude item.  
<sup>n</sup> : negative attitude item.

Twenty five (11%) of participants had good practice score while 198 (88.8%) had low practice score in which only 8 (3.6%) of the participants had sent suspected ADRs reports to Ministry of Health (MOH) or manufacture companies (Table 4).

**Table 4: Responses to the practice related questions**

Questions	Frequency	Percentage
1. Have you ever diagnosed an ADRs within the last 12 months?	64	28.7
2. Have you ever sent a suspected ADR report to MOH or manufacturer?	8	3.6
3. Have you ever reported any ADRs related to OTC or herbal products in the last 12 months?	6	2.7
4. Have you ever reported a new ADR (not mentioned in drug leaflet) for any drug?	2	0.9
5. Have you ever prevent any serious ADRs?	100	44.8
6. Have you read an article related to ADRs in the last 12 months?	103	46.2
7. Have you ever counselled patient regarding ADRs in the last 12 months?	175	78.5
8. Have you ever counselled patient regarding food /drug interaction in the last 12 months ?	196	87.9

There was a positive correlation between knowledge and attitude ( $\rho=0.141$ ,  $p<0.05$ ) and between knowledge and practice ( $r=0.171$ ,  $p<0.001$ ). There was no association between attitude and practice.

#### **IV. DISCUSSION**

This is the first study of its kind in the UAE that evaluated the KAP of the CPs regarding PV and ADRs reporting. What was evident from the present study is that there are gross problems with reporting ADRs by the UAE CPs. The study outcomes revealed that CPs had poor knowledge towards ADRs reporting and PV activity, which is compatible with previous studies [16, 29, 30].

Approximately half of the surveyed CPs (55.9%) were not aware of the Health Authority in Abu Dhabi (HAAD) PV program in the UAE. This finding was reasonably similar to the observation made in Malaysia where about 59.3% of the participants were not aware of the availability of PV center in their country [31]. On the other hand, the figures in the present study were lower than the figures reported in Saudi Arabia (86.8%) [16], and far higher than figures reported in Holland and in UK [19, 32]. In Holland only (1%) CPs were not aware of the availability of national PV Centre [19]. In UK (7%) CPs were not alert about the existence of national PV program [32]. These results may point to inadequate program announcement to CPs which emphasizes on the urgency of developing strategies to increase the knowledge about PV center availability in the country.

In addition, the study findings had revealed that none of the pharmacists correctly defined the ADRs term and only 28 (2.6%) of the pharmacists claimed to know the difference between ADR type 1 and ADR type 2, while in fact 15 (6.7%) pharmacists were able to define correctly the difference. The finding of the study did not differ from studies in other countries [16, 31].

It was found in this current study that 186 pharmacists (83.4%) do not know how to report ADRs. Similar findings have been reported in China [25] where majority of the participants were having poor knowledge on how to report ADRs. Unlike findings of other studies conducted at UK [26] and Australia [23] where the participants showed adequate knowledge on how to report ADRs. These findings advocate the need for awareness programs for the pharmacists about ADRs reporting. The awareness program should focus on the filling method of the ADRs form and the details of the reporting procedure.

Very often, the uncertainty about the causality between the ADRs and the drug was one of the reasons for under-reporting of ADRs [33]. Thus; it becomes necessary to make the pharmacists alert about how to perform the causality assessment for ADRs. One of the common scales used for causality assessment is the Naranjo algorithm [31]. The present study found that only one community pharmacist (0.4%) was aware of the Naranjo algorithm, while another study showed that 30.3% of the participants were aware of Naranjo algorithm [31]. In this study, none of the CPs were aware of the severity assessment scale.

It can be ascertained that under-reporting of ADRs in UAE is not due to negative attitudes of the pharmacists themselves as the findings of the study reported a positive attitude of CPs towards ADRs reporting. The findings of the current study were parallel to other studies at UK [14, 23] where pharmacists showed a

positive attitude towards ADRs reporting but different from the study done at New Zealand, where negative attitude was observed among pharmacists [27].

When it came to specific professions roles, 193 of the surveyed pharmacists (86.5%) felt that CPs should be involved in ADRs reporting process; in addition, the study found that 199 of the respondents (89.2%) believed that ADRs reporting is a part of the professional role of pharmacists. These results were much related to data reported for CPs in Saudi Arabia [16] where the vast majority of pharmacists (90%) considered ADRs reporting a part of their professional role as pharmacist. On the other hand, outcomes from previous studies were stronger [2, 19] in which all the participants (100%) considered ADRs reporting a part of the professional role of a pharmacist. CPs prime responsibility is ensuring patient safety which can be achieved by active and voluntary participation in the PV program. However, it is the responsibility of the PV center to keep up this positive attitude of the pharmacists, by informing them about the great value of reporting in morbidity and mortality reduction and by bringing up-to-date related PV news.

Although MOH did not want to receive reports of only proven ADRs, 94.5% of the pharmacists indicated that they must be sure of the causality between the drug and ADRs before reporting. This finding is consistent with previous findings reported about pharmacists in other countries like Saudi Arabia [16], which reflect the fear of the reporter of appearing unwise and irrational. This negatively-believed attitude should be addressed extremely in any informative workshops to alleviate pharmacists anxiety and to strengthen their clinical confidence in reporting ADRs.

It was disappointing that a negative sign was revealed by this survey as a large proportion of pharmacists 97.3% were not willing to report ADRs caused by the OTC. Unlike pharmacists in Saudi Arabia, where majority of them were willing to report ADRs related to OTC products [16]. This finding suggests urgent need to educate pharmacists about reporting guidelines and to encourage them to report all reactions for all drugs including new drugs, OTC and herbal products.

Another negative sign discovered in this study was that (96.9%) CPs expressed their concerns for the need to discuss any suspected ADRs with a physician, even though they are not required to do so before submitting the report to HAAD PV center. The finding of the present study reflects the lack of confidence and fears of legal consequences. Similar findings were reported by previous surveys [16,19]. Discussion with physician concerning reporting ADRs by CPs should not be part of the program, since this may become an obstacle for reporting as well as pharmacist reliance on the physician judgment [16].

The positive attitude towards ADRs reporting has indicated that pharmacists were keen and eager to learn and practice if knowledge about ADRs reporting is conveyed to them and that they are sufficiently prepared and assisted. Their willingness was indicated by the fact that the majority (86.1%) of the pharmacists were agreed to attend additional courses or workshops on PV with the purpose of improving their talent to spontaneously report ADRs.

The study showed that the practice score among the surveyed pharmacists were very low (11.2%). In Malaysia only one pharmacist submitted ADR report to the regulatory authority [30]. The finding of this study has indicated very low participation (3.6%) in reporting ADRs. Thus it was not surprising to find that only 0.9% of pharmacists claimed to report a new ADR for drugs and that only 2.7% had submitted ADRs reports related to OTC and herbal products.

One of the important findings revealed in the study was the positive correlation between Knowledge and attitudes towards ADRs reporting. Thus if the knowledge of ADRs reporting is improved then the pharmacists attitude will also improve which would be reflected on ADRs reporting schemes in a positive manner. In distinction, [16, 24, 26] reported poor knowledge level among pharmacists and positive attitude towards PV.

The present study has found association between knowledge and practice toward ADRs reporting. This finding is not parallel with a previous study [25] where the majority of respondents irrespective of their knowledge on ADRs reporting have never reported any ADRs to any place.

The present study discovered no significant relationship between attitude and practice towards ADRs reporting, meaning those participants who have never practiced reporting ADRs were likely to have an equal chance of having a positive attitude towards ADRs reporting. This finding is consistent with other findings [23, 36].

## V. CONCLUSION

**RECOMMENDATIONS:** The PV HAAD center should make sure that all pharmacists are qualified and knowledgeable about PV and ADRs reporting. They have to make sure of the availability of the reporting forms by distributing them to the medical offices, community pharmacies, drug stores, hospitals and any other health providing system. The Ministry of Higher Education should find measures to review and improve pharmaceutical schools curricula to guarantee the incorporation of PV and ADRs reporting system conception. Pharmacy Council should include PV in continuous pharmaceutical education as a part of license requirements for pharmacists in UAE.

**LIMITATIONS:** The major limitation of this study is that the findings were restricted to only community pharmacists working in two cities in UAE, Sharjah and Ajman. The outcomes would have been more significant if the study was conducted in all UAE cities.

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