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Adverse Drug Reaction Reporting among Iranian

Pharmacists: Investigation of Barriers and Attitudes

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ABSTRACT

Adverse drug reaction (ADR) has been known as a main reason to mortality, which pushes a significant pressure on health care resources; in addition reporting ADR could be helpful to decrease the consequences. The present study aimed to determine the attitude and barriers of not reporting ADR cases among a group of Iranian pharmacologists. This cross-sectional study was conducted among 117 pharmacists during 2014. Participants were selected in random sampling with probability proportional to size among pharmacy in the west of Iran. Data were collected by using questionnaire in self-report. Data were analyzed by SPSS version 21 using t statistical tests and bivariate correlations. Mean score of the ADR report barriers was 17.82 years (ranging from 7 to 35 years). Lack of motivation, not having report forms available, inefficiency of reporting and lack of investigations received higher scores as major barriers. Also, increasing the trust between patients and pharmacist, decreasing health care system charges and efficiency had the highest mean scores considering attitudes. Generally, there was a meaningful statistical relationship between reporting ADR by pharmacist and barriers (P = 0.007). According to the results from the present study, it seems essential to hold retraining programs in order to improve reporting ADRs by pharmacists, introducing advantages of reporting ADRs and removing barriers to report ADRs.

Key words: Adverse Drug Reaction, Pharmacist, Barrier

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1. INTRODUCTION

onsidering the definitions by WHO adverse drug reaction includes all negative, random and unexpected effects a drug may have on human which could be observed in doses used to prevent diagnosis and treatment (1). Studies showed that 2.6 to 5.6 percent of receptions in hospitals were due to ADR and almost 35 percent of admitted patients in hospitals had the experience of ADRs (2). Immediate reporting of undesirable reactions of basic and fundamental drugs is a part of drug safety studies; it should be mentioned that it is easy and reasonable to implement the system which includes all drugs and patients. However, the major

problem in this system is lack of reports on consequences and no estimations of ADR outbreaks (3, 4). It was estimated that only 6 to 10 percent of all ADRs were reported (5). Results of a study showed that 81 percent of specialists diagnosed ADRs, but did not report them (6). Avoiding reporting ADRs is a common problem in drug care programs (7, 8). Unfortunately, it has not been considered efficiently in Iran; adverse drug reaction monitoring center (ADRMC) in Iran started its activity since 1998 as a major member of WHO drug monitoring program, and 17967 ADRs were collected and evaluated until 2009, though according to WHO scales it is still smaller than the standards (9). Pharmacists as the first

individuals facing treatments with drugs are evaluated and studied to efficiently and safely use drugs; their knowledge over drugs enables them to efficiently participate in reporting ADRs (6). There are some barriers such as expenses, time, facilities, range of needed changes and etc. preventing accomplishment of a behavior. These barriers could be evaluated by the individual and may lead the individual to avoid the desired behavior. Barriers include the negative aspects which are potential and may avoid following a behavior. Recognizing these barriers could be an instruction to education planners to plan behavior reform interventions (10). Attitude, on the other hand, is defined as acceptance or avoidance of a behavior from an individual point of view which stems from their positive or negative beliefs to accomplish a certain behavior (11). Comprehensive health care programs need to focus on mental factors mediating and predicting behaviors (12-16). Planners and designers' recognition of the reasons and attitudes which make pharmacists avoid reporting ADRs could be seen as a functional instruction to help them plan retraining courses and remove the barriers against reporting ADRs; therefore, considering the importance of the issue, the present study aims to determine the attitude and barriers to reporting ADRs among pharmacist in the west of Iran.

2. MATERIALS AND METHODS

It is a descriptive-sectional study investigating 117 pharmacists working in drugstores in west of Iran. Participants were selected through clustering the different provinces west of Iran and using simple randomized sampling method proportional to size of each cluster. Planned questionnaires, later, were delivered to the samples and data were collected. Samples were justified on study methodology, security of the information and goals of the study. The questionnaire used to gather data included three parts and data was collected through students self-reports. The first part of the questionnaire has investigated the demographic information of the

participants; the second part studied the barrier to report ADRs, and the last part included the items estimating attitude. The research team made use of previous studies on the field (17) to design the items investigating barriers to report ADRs and attitudes to reporting the consequences of ADRs based of 5 item response Likert scale. Barriers were checked using 7 items, for instance, no report form available, or fear of accepting the responsibility, which included the score range from 7 to 35 where the higher the score the more the barriers to report ADRs. Attitudes were checked through using 8 items, for example, reporting ADRs leads to better relationships with the doctors, or there would be prosecution for the reporter; the scores ranged from 8 to 40 where the higher the score, the more positive the attitude to report ADRs. To investigate the reliability of the questionnaires, a preliminary study was accomplished on 20 pharmacists and alpha Cronbach coefficient of ADR barriers questionnaire was estimated to be 0.67; also, alpha Cronbach coefficient for attitude questionnaire was 0.74. Data were analyzed by SPSS version 21 using t statistical test and bivariate correlation, at 95% significant level. Descriptive statistics analyses were used to summarize and organize the data. Bivariate correlations were computed to ascertain the magnitude and direction of the associations between the barrier to ADR report and attitude towards the ADR report. Furthermore, t statistical test was performed for the evaluation the association between ADR report by pharmacists with barriers, and attitude.

3. RESULTS AND DISCUSSION

The mean age of respondents was 37.35 (SD: 10.55) ranged from 23 to 62 years. Participants included 52.1 female and 47.9 percent male pharmacists. Almost, 27.4 percent were single and the rest were married. Table 1 shows demographic information investigated in the questionnaire.

Table 1. Distribution of the demographic characteristics among the participants

Variables		Number	Percent
	23 – 30	42	35.9
	31 - 40	30	25.6
Age group	41 - 50	32	27.4
	Upper 50	11	9.4
	Unanswered	2	1.7
	Under 1 year	8	6.8
	1-5 year	34	29.1
- 4	6-10 year	21	17.9
Job History	11 – 15 year	14	12
	16-20 year	10	8.5
	Upper 20 year	15	12.8
	Unanswered	15	12.8

	Male	61	52.1
Sex	Female	56	47.9
	Single	32	27.4
Marital Status	Married	85	72.6
	Weak	8	6.8
	Average	29	24.8
Economic Status	Good	67	57.3
	Very Good	9	7.7
	Unanswered	4	3.4

Results from the present study showed that participants mean scores for barriers of ADR reporting questionnaire was 17.82 (SD: 4.77). Table 2 shows the results of studying the barriers to report ADRs. As seen in table 2,

lack of motivation, not having reporting forms available, inefficiency of reporting and lack of later monitoring got the highest mean scores among barrier items.

Table 2. Assessment of ADR Report Barriers Items among the Participants

ADR Report Barriers Items	1	2	3	4	5	Mean (SD)
Inaccessibility to ADR reporting	32 (27.4 %)	25 (21.4 %)	25 (21.4 %)	15 (12.8 %)	20 (17.1 %)	2.70 (1.43)
forms						
Time consuming procedure to	30 (25.6 %)	35 (29.9 %)	39 (33.3 %)	6 (5.1 %)	7 (6 %)	2.35 (1.10)
report ADRs						
Fear of accepting the	36 (30.8 %)	30 (25.6 %)	37 (31.6 %)	14 (12 %)	-	2.24 (1.02)
responsibility						
Lack of motivation	11 (9.4 %)	18 (15.4 %)	42 (35.9 %)	25 (21.4 %)	21 (17.9 %)	3.23 (1.91)
Lack of knowledge on reporting	33 (28.2 %)	30 (25.6 %)	41 (35 %)	11 (9.4 %)	2 (1.7 %)	2.30 (1.03)
procedure						
Lack of confidence to the reason	37 (31.6 %)	28 (23.9 %)	32 (27.4%)	13 (11.1 %)	7 (6 %)	2.35 (1.20)
of the drug events						
Inefficacy of reporting due to	21 (17.9 %)	36 (30.8 %)	33 (28.2 %)	21 (17.9 %)	6 (5.1 %)	2.61 (1.12)
lack of monitoring						

Table 3 represents the attitudes to reporting ADRs. Results showed that increasing the reliance to pharmacists, decreasing expenses of health care system and efficiency

gained the highest mean scores among other items.

Table 3. Assessment of ADR Report Attitude Items among the Participants

ADR Report Attitude Items	1	2	3	4	5	Mean (SD)
Higher safety of the patients	9 (7.7 %)	36 (30.8 %)	68 (58.1 %)	4 (3.4 %)	-	2.57 (0.68)
Better relationships with	26 (22.2 %)	38 (32.5 %)	36 (30.8 %)	13 (11.1 %)	4 (3.4 %)	2.41 (1.05)
pharmacists						
Efficiency	2 (1.7 %)	15 (12.8 %)	37 (31.6 %)	20 (17.1 %)	43 (36.8 %)	3.74 (1.13)
No trust between patients and	6 (5.1 %)	16 (13.7 %)	68 (58.1 %)	21 (17.9 %)	6 (5.1 %)	3.04 (0.85)
doctors						
Prosecution of the reporter	7 (6 %)	9 (7.7 %)	29 (24.8 %)	51 (43.6 %)	21 (17.9 %)	3.59 (1.05)
Increasing patients reliance to	2 (1.7 %)	2 (1.7 %)	31 (26.5 %)	24 (20.5 %)	58 (49.6 %)	4.14 (0.98)
pharmacist						
Decreasing health care expenses	-	4 (3.4 %)	36 (30.8 %)	27 (23.1 %)	50 (42.7 %)	4.05 (0.93)
Growing dissatisfaction between pharmacist and doctor	15 (12.8 %)	12 (10.3 %)	34 (29.1 %)	36 (30.8 %)	20 (17.1 %)	3.29 (1.23)

Table 4 studies the relationship between barriers and reporting ADRs, and, also, attitude and reporting ADRs among pharmacists. As the results showed, there was a meaningful relationship among barriers and reporting

ADRs (P = 0.007); though there was no statistically significant difference between attitude and reporting ADRs (P = 0.831).

Table 4. Association between ADR Report by Pharmacists with Barriers, and Attitude

	ADR Report	Mean	SD	t	P
Barriers	Yes	15.56	4.09	-2.757	0.007*
	No	18.44	4.77		
Attitude	Yes	27.04	5.35	0.215	0.831
	No	26.80	4.73		

In addition our findings based on bivariate correlation showed the barrier to ADR report was associated with the attitude towards the barrier to ADR report (r = -0.206), were statistically significant at either 0.05 level. Diagram 1 shows ADR reporting among pharmacists which suggests that 21.4 percent of them had the experience of reporting ADRs.

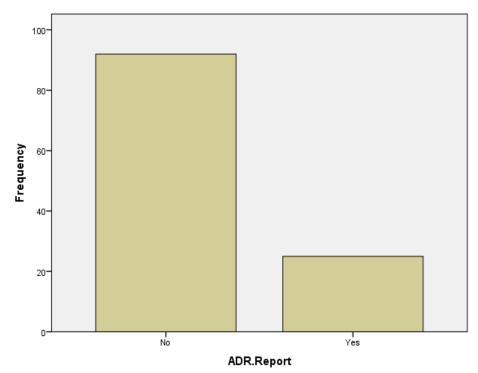


Diagram 1. ADR report status among the participants

As it was earlier mentioned, the present study aimed to determine the barriers of reporting of ADRs among a group of Iranian pharmacists. Results from the present study showed that lack of motivation, inaccessibility of reporting forms, inefficiency of reports and lack of later monitoring had the highest mean scores among barrier items, respectively. In this regard, Goyal et al. reported that several factors including fatigue, being busy, time issues, being worry on prosecution and lack of enough information on reporting procedure were considered as barriers to report ADRs (6). On the other hand, it should be note that considering to training needs of the target group, a practical guide could help planners to create efficient and practical training programs (18). In general, results from the present study showed that reporting ADRs had a statistically meaningful relationship with barriers, which

demands for more attempts to remove them. In this regard, based on the findings of the present study, the major barrier to reporting ADRs was lack of motivation to report ADRs among pharmacists participating in the study, which could be improved through holding retraining courses and also developing supportive systems to pharmacists who report ADRs. Accordingly, Etminani Esfahani et al. studied a group of pharmacy students in Iran and suggested that more than 70 percent of them were not satisfied with reporting ADRs and, also, 60 percent believed that educational interventions could improve the number of reports on ADRs (1). These findings emphasize the importance of holding retraining courses on the issue. The other barrier which gained a high mean score among participants was inaccessibility of the ADR reporting forms. Designing simple and practical forms or developing online reporting systems by drug assistance in Medical Science universities could improve reporting rate among pharmacists. The third barrier with the highest mean score among pharmacists was inefficiency of the reports on ADRs and lack of later investigations. It seems that holding retraining courses and developing sensitivity to advantages of reporting ADRs among pharmacists could be helpful to improve health care system in Iran. Also, regular verifications of ADR reports by administrators may help to overcome the problem. Attitude has been defined as combining knowledge, feelings and preparations to act against a certain thing in an individual (11). Findings from the present study showed that increasing the trust of patients to their pharmacists, decreasing health care expenses and efficiency gained the highest mean scores among other attitude items. Based on the results, it could be concluded that pharmacists had a positive attitude to reporting ADRs; therefore, training courses should focus on removing mentioned barriers to improve reporting ADRs among pharmacists.

4. CONCLUSION

It seems that holding retraining courses for pharmacologists and introducing educational programs with improving their sensitivity to the efficiency of reporting ADRs in order to enhance health care system in Iran, motivating them to regularly report ADRs, making the needed forms available to report ADRs, and a better observation of gained reports by drug deputy could lead in more effective results to remove barriers preventing pharmacologists to report ADRs.

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AUTHORS CONTRIBUTION

This work was carried out in collaboration among all authors.

CONFLICT OF INTEREST

The authors declared no potential conflicts of interests with respect to the authorship and/or publication of this article.

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