

Factors related with adverse drug reaction reporting: a cross-sectional study among pharmacists in the West of Iran

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ABSTRACT

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; which report it could be helpful to prevent and decrease the side effects. The aim of this study was to determine the prevalence and factors related with adverse drug reaction reporting among pharmacists.

In this cross-sectional study, conducted in the west of Iran, a total of 117 pharmacists, were randomly selected to participate voluntarily in the study during 2014. Participants filled out a self-administered questionnaire. Data were analyzed by SPSS version 21 using bivariate correlations, logistic and linear regression statistical tests. Almost 21.4% of the participants had history of adverse drug reaction reporting. The best predictors for adverse drug reaction reporting was perceived behavioral control (OR: 1.227) and attitude (OR: 1.164). In addition, attitude was the best predictor for intention to adverse drug reaction reporting among pharmacists (B: 0.490 & P: 0.001). Based on our result, it seems that designing and implementation of retraining programs to improve positive attitude towards adverse drug reaction reporting and incensing pharmacist's behavioral control to adverse drug reaction reporting may be usefulness of the results in order to promotion of adverse drug reaction reporting.

Keywords: Adverse drug reaction reporting, Pharmacists, Attitude, Perceived behavioral control.

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Introduction

According to the World Health Organization's definition, side effects (Adverse Drug Reaction - ADR) are any potentially harmful, random and unexpected a drug may have on human which could be observed in doses used to prevent diagnosis and treatment (1). Studies showed that 2.9-5.6% of hospital admissions are due to adverse drug events and nearly 35 percent of

hospitalized patients experience side effects (2). Immediate reporting of adverse drug reactions is the foundation of drug safety studies, it should be noted that it is low-cost and easy to implement this system which can expanded to all types of drugs and all patients. But the fundamental problem of this system is first, failing to report side effects and the second, the lack of estimation

for possible prevalence (3, 4). It has been demonstrated that only 6 to 10 percent of all adverse drug reactions is reported (5). The results of another survey showed that 81 percent of specialists detected medication side effects but they had not reported those (6); failing to report side effects is a common problem in medical care program (7, 8). Unfortunately, in Iran there has not been enough attention to this matter; in Iran Adverse Drug Reaction Monitoring Center (ADRM), started its activity as a full member of the international drug monitoring program of the World Health Organization, in 1998. Until 2009, 17967 adverse drug events was collected and evaluated by this center, although, based on WHO criteria this amount is still below the standard level (9). Pharmacists are evaluated as the first-line agents of drug therapy for safety and efficacy of drugs, their knowledge of the drugs has enabled them to participate effectively in reporting side effects [6]. In order to have good efficacy, comprehensive programs of education and communication requires an emphasis on mediation and psychological factors which are predictors of behavior (15-10). It should also be noted that the most effective programs are theory-driven approaches which are based on behavior change models (16). In the meantime, one of the theories that have been used in several studies to predict the behavior is the theory of planned behavior, the theory of attitude (pointing to an overall feeling of love or hatred toward any certain behavior), subjective norms (refer to the person's belief about the most important people in his life, think he should or should not pay to perform the desired behavior), perceived behavior control (refer to the issue of how a person feels that collided established in accordance with the specified behavior),

behavioral intention (including thinking and behavior which indicate strongly the intention and will of the individual to do the behavior and considered as the determining factor to perform a certain behavior) has been established which predict the occurrence of a specific behavior (17). There have been several reports of the applicability of the theory of planned behavior to predict drug side effects in other populations (20-18). Due to the fact that awareness of planners and designers about predictive factors of side effects, reported by pharmacists, can provide valuable information for planners to design retraining courses and remove existing barriers to report drug side effects. Lack of information in this regards in Iran, this study was conducted to determine the reported adverse drug reactions as well as its predictive factors among a group of pharmacists in the West of Iran based on planned behavior theory.

Materials and Methods

In this cross-sectional study, a total of 169 pharmacists in the West of Iran in 2014 were included. The sample size of the present study according to the results of a pilot study, with 95% accuracy and senility 0.05 was 169. After eliminating incomplete questionnaires, 117 questionnaires were analyzed (response rate in the present study was 69.2 percent). In this study, the different provinces in the West of Iran was intended cluster using simple random sampling with probability proportional to size in each cluster, participants (officials Technical pharmacies) were selected and designed questionnaires were provided to them and required data and information were gathered from them at the end. The subjects of the study and confidentiality of information was justified

and all of them were enrolled with complete awareness and desire. Data collection included three parts and self-report data were collected from the participants. The first section includes background information (ten questions about participants' individual information) and information such as age (years), sex (male or female), marital status (single, married), economic status (very poor, poor, average, good, very good), parental education (no education, high school diploma, diploma, university studies), duration of work experience in pharmacy (months), the average hours the participant works per pharmacy per week (hours), average monthly wage in the pharmacy (USD), average Pharmacy-related studies during the week (hours), and history of the pharmacist in the family (yes, no) were measured. The second part consisted of two questions (the history of attending the workshop related to the side effects and the second was the reporting of side effects), which was assessed as yes and no. The third part contained 19 questions relating to the structure of the theory of planned behavior in four parts. The research team utilized the theory studies (20-18). They completed and designed questionnaires based on "Likert" style questionnaires form with scale response above five scores for attitude, subjective norm, perceived behavioral control and intention. Reliability of the questionnaire was evaluated on a pilot study on 20 participants using Cronbach's alpha and this reliability of the questionnaire was confirmed as described later: content validity was confirmed by an expert groups (including a pharmacist, a specialist in health education and health promotion, specialist in internal Medicine and PhD in Health Services management). Attitude contained eight items, for example "report side effects can be prosecuted for reporting to be followed", which included the

score of 8 to 40 and earned a higher score indicated more favorable attitudes toward drug side effects reporting. Cronbach's alpha coefficient attitude (0.74) was approved. Subjective norms, included four items, for example, "If I were serious to report harmful incidents drug effects, other pharmacists would confirm that". Included the range of 4 to 20 score and earning a higher score represented a subjective norms encouraging complications adverse drug. Cronbach's alpha coefficient attitude (0.77) was approved. Perceived behavioral control contained four items, for example, "to me it is difficult to report the Food and Drug Department, in case I face drugs with serious incidents damaging side effects". The score ranged from 4 to 20 were included and earning more score indicated higher perceived behavioral control side effects in reporting. Cronbach's alpha coefficient attitude for perceived behavioral control (0.80) was approved. The intention of behavior included three items. For example, "I am going to report the serious side effects of drugs, in case I face with them" which included the score of 3 to 15 and earning a higher score indicated more behavior intended to report the side effects of the drug. Cronbach's alpha coefficient of behavioral intention questionnaire was 0.82. The data collected were entered into SPSS version 21 using Pearson correlation, and logistic regression analysis. The P value of 0.05% was considered as a significant level.

Results

The average age of participants was 35.37 with a standard deviation of 10.55 year, ranging from 23 to 62 years. 52.1% of the participants were female and 47.9 percent of them were male. In terms of marital status, 27.4% of them were unmarried and rest of

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them was married. According to our findings, 21.4 percent of pharmacists had history of reporting the drug adverse effects. In addition, 49.6 percent of them indicated that they had participated in workshops related to adverse drug events. In Table 1, the correlation between the theories of planned behavior has been studied and as it is shown, behavioral intention reported side effects had strongest correlation with attitude.

The results of logistic regression analysis (Backward Stepwise Wald method) showed that among the three structures, attitudes, subjective norms and perceived behavioral control, two perceived behavioral control constructs (OR=1.227)

attitude (OR=1.164) are stronger predictor for adverse drug events reported among pharmacists (table 2).

Finally, we used linear regression analysis (Backward method) to determine the effect of attitude structures, subjective norms, and perceived behavioral control on behavioral intention among pharmacists reported side effects. And based on the results of the above structures, 45% of behavioral intention variance report side effects predicted behavioral intention, which in the meantime attitudes was stronger predictor of behavioral intention among pharmacists reported side effects (table 3).

Table 1. Correlation between the structure theories of planned behavior regarding the reported side effects

Variables	Attitude	Subjective norms	Perceived behavioral control
Attitude	1		
Subjective norms	0.203*	1	
Perceived behavioral control	0.382*	0.238*	1
Behavioral intention	0.611*	0.294*	0.464*

* The correlation was significant ($P > 0.05$) (2-Tailed)

Table 2. Logistic regression analysis of structures attitudes, subjective norms, and perceived behavioral control as a predictor of future behavior among pharmacists surveyed reported side effects

Stage	Variables	β	B (SE)	Wald	P value	OR	95.0% C.I. for EXP(B)	
							Lower	Upper
First	Attitude	0.148	0.065	5.262	0.022	1.160	1.022	1.317
	Subjective norms	0.070	0.095	0.545	0.460	1.073	0.890	1.293
	Perceived behavioral control	0.193	0.100	3.717	0.054	1.213	0.997	1.475
	Constant	-9.263	2.298	16.251	0.001	0.001	---	---
	Attitude	0.152	0.065	5.478	0.019	1.164	1.025	1.321
Second	Perceived behavioral control	0.204	0.100	4.188	0.041	1.227	1.009	1.492
	Constant	-8.619	2.078	17.195	0.001	0.014	---	---

Table 3. Linear regression analysis was done to determine the role of structures, attitudes, subjective norms, and perceived behavioral control on intentions of ADR reporting among pharmacists

Structure	Un standardized Coefficients		Standardized Coefficients	t	P-value
	B	Std. Error	Beta		
Constant	-0.779	1.286	-	-0.606	0.546
Attitudes	0.261	0.040	0.490	6.454	0.001
Subjective norms	0.131	0.070	0.136	1.889	0.061
Perceived behavioral control	-0.217	0.068	0.245	3.202	0.002

Adjusted R squared = 0.45, $F = 31.188$ & $P < 0.001$

Discussion

Results showed that 21.4 percent of pharmacists had history of reporting the drug side effects. In this regard Gavaza and colleagues reported that 32 percent of pharmacists surveyed had a history of reporting medical complications (18). Belton et al. demonstrated this rate was 33.2 percent in Dutch doctors (22). Bäckström et al. study also showed that a history of reported adverse drug side effects among general practitioners in Sweden were 33.7 percent (23). These rates are higher than those reported in our study. In another study, Lee and colleagues showed that among pharmacists in Hong Kong, despite the fact that 93 percent of pharmacists surveyed believed that the reporting side effects are important, but only 14.7% of them reported a history of drug effects in over the past year (24). These findings show that there are obstacles in the way of reporting adverse drug reactions among pharmacists. Moreover, due to the multiple benefits of reporting drug side effects in the health care system, this low rate could be an alarm for health care services in the country and the need to pay more attention to this problem and to identify obstacles and predictors of adverse drug reports in order to provide communication approaches among physicians and pharmacists to improve drug effects reporting. As the findings showed, overall 45% of the variance in intention report drug side effects predicted by structures attitudes, subjective norms, and perceived behavioral control; which attitude and behavior control planned had a stronger role among them. The results of logistic regression analysis showed that attitude and perceived behavioral control are more robust structures to predict side effects among pharmacists surveyed. In this regard, Gavaza and etal. Study on pharmacists in Texas, USA,

demonstrated that, Pharmacists who has more favorable attitude to the fact that this reporting can improve outcomes in patients were more likely to report the side effects than others (21). The results of another study by Gavaza and colleagues indicated that among pharmacy students in Virginia, the majority of them believed that they can improve the health of patients by reporting side effects, but this may interfere in the relations with the doctor (19). Moreover, Gavaza etal used the planned behavior theory to examine the predictors of adverse drug reactions reported among pharmacists and their study findings showed that attitude and subjective norms was powerful predictor of adverse drug reactions; Their findings also showed that the structure of attitudes, subjective norms, and perceived behavioral control predicted 34 percent of the behavioral intentional variance of adverse drug reactions (18). On the other hands, our study showed that subjective norms were not a strong predictor of behavioral intention in pharmacists for reporting the adverse drugs reactions. This finding is not consistent with the results of Gavaza et al. reported that subjective norms after attitudes are the strongest factor in predicting behavioral intention in pharmacist to report adverse drug reactions (18). Wu and colleagues demonstrated that subjective norms were the most powerful predictor of behavioral intention of pharmacists in reporting adverse drug reactions (20), which is not in line of our findings. Given the important role of attitudes in predicting drug side effects among pharmacists conducting retraining courses as well as providing support systems for pharmacists reporting them, can be more effective in reporting adverse drug reactions by pharmacists. In this regard, study of Etminani and colleagues on pharmacy students in Iran showed that, more than 70 percent of them

did not have satisfactory knowledge of drug side effects and 60% of them believed that educational interventions can be helpful in increasing drug complications reports (1).

Conclusion

These findings demonstrate the needs of retraining courses for pharmacists in the field in Iran. Due to lack of information on adverse drug reactions reports among pharmacists in Iran, the findings of the present study is very informative, although it has some limitations as well. One could be the fact of gathering information through questionnaires (Which can be associated with a percentage of error in the response by the participants) and relatively high sampling loss was also another limitation.

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Conflict of Interest

Not Declared.

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