An educational intervention to improve nurses' knowledge, attitude, and practice toward reporting of adverse drug reactions

Somayeh Hanafi[1], Hassan Torkamandi[1], Alireza Hayatshahi[2], Kheirollah Gholami[2,3], Nikinaz Ashrafi Shahmirzadi[1], Mohammad Reza Javadi[1,2,3]

ABSTRACT

Background: The reporting of adverse drug reactions (ADRs) by nurses in hospitals is very important.
Aims: This study was aimed at investigating the impact of an educational intervention to improve ADR reporting and whether trained nurses had better knowledge, attitude, and practice toward ADR reporting.
Materials and Methods: A total of 300 nurses in a tertiary care teaching hospital in Tehran, Iran were evaluated with a knowledge, attitude, and practice (KAP) questionnaire regarding ADR reporting in March 2010. After this, an educational program about ADR was provided to nurses. Then the nurses were re-evaluated by the same questionnaire. Comparisons were made of the attitude and knowledge within nurses, before and after education. Data were analyzed using SPSS software. $P < 0.05$ was considered as significant level. Independent-sample *t*-test was used to measure the intervention effect.
Results: The response rate was 61.3% (N = 184). Knowledge of nurses before the intervention was significantly less than the knowledge after the intervention (P = 0.001). Also, there was a significant effect on attitude (P = 0.002). During the follow-up period of 4 months after the intervention, 26 spontaneous reports were received.
Conclusion: Continuous ADR educational program, training, and integration of ADRs' reporting into the activities of the nurses would likely improve ADR reporting.

Key words: Adverse drug reaction, educational assessment, nursing personnel

INTRODUCTION

World Health Organization's (WHO's) definition of an adverse drug reaction (ADR) is "a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or treatment of a disease, or for modification of a physiological function."[1] ADRs are one of the leading causes of morbidity and mortality. It has been estimated that around 2.9-5.6% of all hospital admissions are due to ADRs and as many as 35% of hospitalized patients experience an ADR during their hospitalization.[2] Fatal ADRs rank among the most common causes of death. The economic burden of ADRs is also considerable; for example, in the United States, the cost of drug-related morbidity and mortality exceeded $177.4 billion in 2000.[3]

[1]Department of Pharmaceutical Care, Dr. Shariati Hospital, Tehran University of Medical Sciences, Tehran, Iran, [2]Department of Clinical Pharmacy, Pharmacy School, Tehran University of Medical Sciences, Tehran, Iran, [3]Research Center for Rational Use of Drugs, Tehran University of Medical Sciences, Tehran, Iran

Address for correspondence: Dr. Mohammad Reza Javadi,
Department of Clinical Pharmacy, Pharmacy School,
Tehran University of Medical Sciences, 16th Azar St., Tehran, Iran.
E-mail: javadirctex@yahoo.com

Spontaneous reporting of ADRs is one of the basic methods for post-marketing surveillance and is a method to generate signals of unrecognized ADRs.[4] It remains the cornerstone of pharmacovigilance and is important in maintaining patient safety. However, reporting of serious ADRs rarely exceeds 10%.[5]

Thalidomide disaster was one of the biggest triggers for the initiation of systematic collection of data on ADRs in 1960s.[6] In Iran, a national ADR reporting system was established by the Ministry of Health in June 1998. Despite the existence of the national ADR reporting system in Iran, a major problem of voluntary surveillance by healthcare professionals has been the high level of underreporting.[2] According to the WHO standards, countries with the best reporting rates generate over 200 reports per 1,000,000 inhabitants per year. Therefore, in Iran, with a population of over 60 million, it is expected to receive at least 12,000 reports per year. Unfortunately this is not so, considering the fact that only 2330 reports were sent to the Iranian Pharmacovigilance Center (IPC) in 2006.[7]

The reporting of ADRs in hospitals is very important because severe ADRs are most likely to be seen in hospitals; ADRs can be detected early on, and spontaneous reports

can be more accurate.[8] Nurses, in their unique position as drug administrators who record the observed effects of drug use, have been found to have an important role in ADR reporting and constitute a potentially valuable source for spontaneous ADR reports in hospitals, Because they are close to the patients and have a good knowledge of patient's health status, symptoms, drugs, and ADRs. They are often the sources in alerting the responsible prescriber about the possible ADRs. There is thus a logical reason to involve nurses and encourage them to contribute in ADR reporting system.[9,10] In this study, we assessed the role of an educational intervention in ADR reporting. We investigated whether trained nurses had better knowledge, attitude, and practice (KAP) toward the reporting of ADRs in comparison with the same group before training.

Materials and Methods

Dr. Shariati hospital is a 598-bedded tertiary care teaching hospital in Tehran, Iran. Prior to 2009, no ADR reporting system was in place. The hospital's pharmacovigilance unit was established in February 2010 to report ADRs.

In our previous study in November 2009, we chose an observational-descriptive research in which a questionnaire was prepared to investigate the KAP of nurses regarding ADR.[11] The questionnaire included the issues addressed in previous studies examining the KAP of medical practitioners to ADR reporting,[7] but were modified to take into account the national basis of the current investigation. For the purpose of the study, the KAP questionnaire was designed by the researchers of the pharmacovigilance in pharmaceutical care department in the hospital through searching in related internet websites. This KAP questionnaire consisted of a total of 17 questions. Among these questions, six were related to the knowledge, seven to the attitude, and the remaining four questions were related to the practice aspects.

Knowledge- and practice-related questions were designed as multiple choices. Knowledge-related questions consisted of easy, moderate, and difficult ones (in equal portions). Attitude-related questions were developed in five choices Likert scale. Content validity (systematic examination of the test content to determine whether it covers a representative sample of the behavior domain to be measured) of the questionnaire was evaluated by expert pharmacists. The initial draft was circulated to the members of the research team and modifications were carried out as per the suggestions. Upon receiving the responses from healthcare professionals, its internal consistency reliability was tested by finding the Cronbach's alpha coefficient on a sample consisting of 20 randomly selected hospital nurses. Test-related reliability was tested by finding the intra-cluster

correlation on the same sample after a week. After this modification, the finalized questionnaire was employed, in order to collect data from the major sample.

We are aware of some studies that evaluated the effectiveness of different interventions aimed at increasing ADR reporting rate among healthcare professionals. However, the design and purposes of these studies vary.[9,12-17] In March 2010, we developed an educational intervention consisting of a 3 h presentation, undertaken by a clinical pharmacologist and a pharmacist specialized in pharmacovigilance, describing the definitions of pharmacovigilance and ADRs; giving a review of international studies on drug-related morbidity and mortality, hospital admissions due to ADRs, and economic importance of ADRs; describing the methods used in pharmacosurveillance and in spontaneous reporting systems, explaining that underreporting constituted the system's major limitation; and conducting a discussion about the most important cases of ADRs reported to the Iranian Pharmacovigilance Center. We also explained the main parts of the Yellow Card and how to complete it while facing a suspected ADR. We encouraged nurses to report all suspected ADRs including those that were mild or anticipated through ADR-reporting Yellow Cards available at all the nursing stations. All nurses of the hospital were invited to participate in this seminar. One month after the educational intervention, the nurses were re-evaluated using the same questionnaire. Comparisons were made of the attitude and knowledge within nurses, before and after the educational program. There was also a follow-up period that began immediately after the intervention. The outcome assessed included an indicator of reporting quantity (total number of records).

Statistical analysis
The filled KAP questionnaires were analyzed by producing descriptive statistics using the Statistical Package for Social Sciences (SPSS) for MS windows version 17. Score one was assigned to the correct answers to knowledge and practice questions and zero was assigned to the wrong answers. The numerical variables (e.g. the number of working hours per month) were described numerically. The answers to attitude questions were ranked from one to five accordingly; so, score five represents the best attitude. In order to determine the effective factors on knowledge (the summary variable of knowledge), the independent variables with entry into the regression model were used. Accordingly, in order to determine the effective factors on attitude, the summary variable of knowledge was added to the series of independent variables, and to determine the effective factors on practice, both knowledge and attitude variables were added to the series of independent variables. The statistical significance level was considered as 0.05 ($P < 0.05$). Independent-sample t-test was used to measure the intervention effect on nurses' attitude and knowledge before

and after the educational program. As it was impossible to compare two samples as person to person, we chose independent-sample *t*-test; otherwise, paired-sample *t*-test is more reliable than independent-sample *t*-test in evaluating an intervention effect.

RESULTS

Demographics

Of the 300 nurses who received the questionnaires, 184 (61.3%) completed the questionnaires. Among these respondents, 94.4% were females. Nearly 95% of all respondents were graduated with Bachelor of Science degree in nursing. The demographic data are shown in Table 1.

Internal reliability for KAP variables was tested by finding the Cronbach's alpha coefficient, which was 0.739, 0.513, and 0.754, respectively. Omission of none of the items in attitude questions could increase the Cronbach's alpha coefficient appreciably.

Knowledge about ADR reporting

Nurses' knowledge toward the ADR reporting was evaluated by using six pharmacovigilance-related questions. The results are shown in Table 2. There was no statistically significant relation between independent variables in linear regression analysis and knowledge of the evaluated population [Table 3].

Attitudes toward ADR reporting

To explore the nurses' attitudes to pharmacovigilance, seven questions were designed. The descriptive results are presented in Table 4. Also, the independent variables which were entered into the regression analysis did not show any correlation with attitude of the evaluated population. The mean and other statistics of the distribution of knowledge and attitude variables is shown in Table 5.

Practice variables

Nearly 12% of the respondents had experienced ADR reporting. Of this group, 90.7% used Yellow Cards for reporting the ADRs, 9.3% used phone, and nobody used internet or fax for submitting the report. One of the questions was regarding the nurses' reactions while facing an ADR. More than 89% (148 out of 165) of the respondents to this question reported that they would prefer to announce the ADRs to the physicians in the ward. Figure 1 shows the distribution of their answers to this question.

Comparison of attitudes and knowledge of the nurses before and after educational intervention

To evaluate the changes in knowledge and attitudes of the evaluated population, the mean scores of the knowledge and attitudes before and after the intervention were compared using independent-sample *t*-test. The results demonstrated that the mean scores of knowledge and attitudes changed significantly after the educational intervention. In other words, it resulted in considerable positive changes in both knowledge and attitudes among the nurses [Table 6].

DISCUSSION

The most important finding in the present study was that an educational intervention resulted in considerable positive changes in both knowledge and attitude among nurses. The maximum knowledge level was about correct definition of the
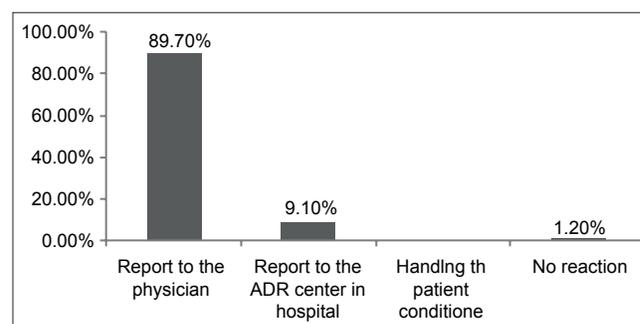

Figure 1: Distribution of the nurses' reactions while facing an ADR

Table 1: Age, years from graduation, working hours per month, length of practice (*N*=184)

Characteristic	Mean±SD	Range
Age (years)	32.6±7.4	22.0-55.0
Years from graduation	10.5±7.5	1.0-30.0
Working hours per month	192.7±41.7	40-350
Length of practice (years)	10.1±7.2	1.0-29.0

SD: Standard deviation

Table 2: Nurses' knowledge about ADR reporting

Knowledge variable	Right answer (%)	Wrong answer (%)	No answer (%)
Correct definition of the term "pharmacovigilance"	98 (53.3)	82 (44.6)	4 (2.2)
The most important way of collecting ADR related information	80 (43.5)	95 (51.6)	9 (4.9)
Yellow Card details	41 (22.3)	141 (76.6)	2 (1.1)
ADR reports' characteristics	97 (52.7)	82 (44.6)	5 (2.7)
Medicine which has the most fatality following occurrence of its ADRs	82 (44.6)	97 (52.7)	5 (2.7)
ADRs that should be reported to ADR center	46 (25.0)	135 (73.4)	3 (1.6)
Average	74 (40.2)	105 (57.1)	5 (2.7)

ADR: Adverse drug reactions

term "pharmacovigilance," ADR reports' characteristics, the medicine which has the most fatality following occurrence of its ADRs, and the knowledge about the most important way of collecting ADR-related information; and the least knowledge level was on the Yellow Card details. Similar trend was shown in our previous study in assessing nurses' knowledge before the educational intervention. It was observed from a study conducted in Taleqani Hospital in Iran that the knowledge of nurses before the educational intervention was significantly less than the knowledge after the intervention, but there was no significant effect on the attitude.[18]

The results of our study also demonstrated that the attitude level toward the effect of educational programs on ADR reporting and more consideration about ADRs occurring in high-risk patients (e.g., elderly, children, and special patients) was at the highest. It is similar to the nurses' attitude before the intervention in our previous study.

More than 89% of the respondents to the question regarding their reactions while encountering an ADR stated that they would prefer to report the ADRs to the physicians in the ward. While in a study by Qing *et al.*, 22.8% of nurses reported ADRs primarily to the hospital pharmacy[19] and 56% of nurses in a similar study by Hajebi *et al.* used to send their reports to physicians in the ward.[18]

We must not lose sight of the sobering fact that about half of the cases of drug-related injury are from potentially avoidable ADRs.[1] The incidence of ADRs reported by physicians and nurses is found to be low.[5,8,10,12,16,20] However, there might be some exceptions. For instance, 41% (*n* = 40/97) of an Indian hospital's doctors had reported suspected ADRs to the pharmacovigilance centers. Also, 89% of the responders were aware of the existence of ADR reporting and monitoring system at their hospital.[21] In our study, ADR reporting over the follow-up period which began immediately after the intervention was constant, maybe with a slight increase in the reporting rate 2 weeks after the educational program. Despite encouraging the nurses to report all suspected ADRs through ADR-reporting Yellow Cards available at all the nursing stations, during the period of 4 months, only 26 spontaneous reports

Table 3: Effective factors on knowledge and attitude of nurses regarding ADR

Model	Unstandardized coefficients		Standardized coefficients	*T*	Sig.
	B	Std. error	Beta		
Knowledge					
(Constant)	15.592	42.096	-	0.370	0.712
Age	0.318	1.211	0.104	0.262	0.793
Gender	15.801	10.249	0.165	1.542	0.126
University	−1.784	5.028	−0.037	−0.355	0.723
Graduation year	0.294	1.175	0.096	0.250	0.803
Education level	−5.763	13.978	−0.047	−0.412	0.681
Activity hours	0.013	0.076	0.021	0.178	0.859
Experience	−0.455	1.225	−0.150	−0.371	0.711
Attitude					
(Constant)	39.070	13.998	-	2.791	0.006
Age	−0.023	0.405	−0.023	−0.057	0.954
Gender	−2.723	3.427	−0.087	−0.795	0.429
University	3.313	1.689	0.207	1.961	0.053
Graduation year	0.392	0.402	0.388	0.977	0.331
Education level	1.524	4.611	0.038	0.331	0.742
Activity hours	0.021	0.025	0.100	0.849	0.398
Experience	−0.254	0.427	−0.251	−0.595	0.553
Knowledge	−0.028	0.032	−0.085	−0.869	0.387

ADR: Adverse drug reactions

Table 4: Nurses' attitudes toward ADR reporting

Attitude variable	Completely positive attitude (%)	Positive attitude (%)	Halfway attitude (%)	Negative attitude (%)	Completely negative attitude (%)	No answer
Fear of legal liability following ADR reporting	20 (10.9)	35 (19.0)	11 (6.0)	71 (38.6)	44 (23.9)	3 (1.6)
Being more considerate about ADRs occurring in high-risk patients (e.g. elderly, children, and special patients)	93 (50.5)	77 (41.8)	11 (6.0)	0 (0.0)	0 (0.0)	3 (1.6)
Effect of educational programs on ADR reporting	113 (61.4)	57 (31.1)	9 (4.9)	0 (0.0)	0 (0.0)	5 (2.7)
No current supervision of ADRs occurring in patients	14 (7.6)	98 (53.2)	22 (12.0)	44 (23.9)	2 (1.1)	4 (2.1)
Inevitability of ADR occurrence in patients	10 (5.4)	40 (21.7)	12 (6.5)	115 (62.5)	2 (1.1)	5 (2.7)
Irresponsibility of healthcare professionals about ADR reporting	72 (39.1)	84 (45.6)	11 (6.0)	10 (5.4)	4 (2.1)	3 (1.6)
ADR role in increasing hospitalization expenses	62 (33.7)	90 (48.9)	17 (9.2)	6 (3.2)	6 (3.2)	3 (1.6)
Average	55 (29.9)	69 (37.5)	13 (7.0)	35 (19.0)	8 (4.3)	4 (2.1)

ADR: Adverse drug reactions

Table 5: Distribution of knowledge and attitude variables (out of 100)

Variables	Knowledge	Attitude
Mean	40.22	45.01
Median	50.00	45.71
Mode	50.00	51.43
Range	100.00	62.86
Minimum	0.00	0.00
Maximum	100.00	62.86
Number	184	184

Table 6: Comparing the mean knowledge and attitudes scores before and after intervention

Factor	Stage	Number	Mean±SD	Sig. (two-tailed)
Knowledge	1	224	24.55±17.06	0.000
	2	184	40.22±23.46	
Attitude	1	224	41.91±9.98	0.002
	2	184	45.01±9.57	

Stage 1: Before intervention Stage 2: After intervention. SD: Standard deviation

were received. Similar results were obtained in a study conducted in Sweden during which in a 12-month period, only 18 ADR reports were submitted by nurses who had received special instruction regarding ADR reporting.[22] In contrast to this, in a study by Tabali *et al.*, an initial 148% increase in the number of ADR reports was observed after the educational intervention.[23] Although the actual number of reported ADRs in our study was small, it was an absolute increase in reporting, considering the fact that in comparison, in the years prior to our intervention, only 12% of the respondents had experienced ADR reporting. In other words, whilst all spontaneous reporting systems are affected by underreporting,[24] we expect more reports because the aim and methods of the reporting and monitoring ADRs was extensively explained to the nurses in advance. The underreporting in the follow-up period may be explained by the extensive workload of nurses. ADR reporting is an activity which may take some time to become fully integrated into nurses' daily routines.

Some studies have used interventions such as mailings, newsletters, oral presentations, verbal reminders, articles in staff newsletters, advertisements, and coordination between healthcare professionals and the hospital pharmacists to increase ADR reporting rate.[12-15] The pharmacists' comments to an open question regarding improving ADR reporting in Green *et al.*, study included: Education and training, spending more time on the wards with patients, more feedback and reminders, encouragement from managers, and increased accessibility of Yellow Cards.[5] Also, doctors in a study by Oshikoya[25] and community pharmacists in a study by Bawazir[26] mentioned education

and training as the most recognized means of improving ADR reporting. Educational intervention has been shown to improve ADR reporting.[14,16] Also, we showed that education is a positive predictor in influencing nurses to report ADRs. Similarly, Green *et al.* showed that pharmacists who had received pharmacovigilance training mostly through internal departmental meetings were more likely to report ADRs and knew more about the purposes of the Yellow Card scheme.[5] The effect of educational interventions may diminish over time. So, periodically repeating educational programs maybe would have a booster effect on ADR reporting. We are planning to conduct monthly educational programs for the nurses. It would be logical to extend this study to other teaching hospitals in Iran to enable us generalize our findings.

CONCLUSION

Hospital reporting programs are necessary to increase awareness of ADR reporting among the physicians and nurses. Enhanced reporting rate will improve overall drug assessment and accelerate earlier detection of serious reactions. Our program was an initiation to create a culture of ADR reporting among the healthcare professionals in the hospital. We showed in our study that nurses can respond to educational strategies designed to meet their training needs and can increase ADR reporting. We are planning for further improvement of our ADR-reporting system by increasing the physicians' and nurses' awareness of ADR monitoring and reporting, interactions between the physicians and nurses with the pharmacovigilance center in the hospital, inclusion of pharmacovigilance into pre- and post graduate continuing education programs, and sending feedback information to reporters.

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