

The knowledge, attitude and behaviours of nurses about pharmacovigilance, adverse drug reaction and adverse event reporting in a state hospital

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ABSTRACT

OBJECTIVE: With the use of any drug comes the possibility of unintended consequences which when harmful are referred to as adverse drug reactions (ADRs). The development of national pharmacovigilance systems is the responsibility of all health workers. The aim of this study was to investigate the knowledge of nurses about pharmacovigilance and attitudes about ADR and adverse event reporting.

METHODS: This descriptive-cross sectional study was performed in 112 nurses working in a public hospital. The questionnaire was applied about pharmacovigilance and adverse drug reactions. The knowledge, attitudes and practices about adverse drug reactions were asked.

RESULTS: The 74.1% of the nurses definition of "severe adverse effect" of drug therapy. The ratio of participants who knew that ADRs are reported to contact person responsible from pharmacovigilance was 34.9%. Although 70.5% of nurses knew the necessity of ADR reporting, the 8% of the nurses knew Turkish Pharmacovigilance Center (TÜFAM). Only 8% of nurses reported ADRs in their professionalism.

CONCLUSION: Although most of the participants knew the importance of ADR event reporting, event reporting was low. These results showed that there is a lack of knowledge about pharmacovigilance. Further studies with different settings and healthcare staff are needed to improve awareness about pharmacovigilance.

Key words: Drug reactions; drug safety; pharmacovigilance.

The World Health Organization (WHO) defined adverse drug reaction (ADR) as harmful, and unwanted reaction of a drug when used in normal doses for human beings. Pharmacovigilance was

defined as a branch of science and related activities interested in the determination, evaluation of drug safety, and taking necessary relevant measures [1-3].

At the beginning of 1900s German scien-



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tist Paul Elrich defined the ideal drug as “a magic bullet” which directly reaches the region of the disease, and does not cause any harm to healthy tissues.” Drugs exert their effects on diseased region, and also harm healthy tissues as well [1]. Firstly in the year 1848, chloroform used during operation performed for the extraction of an ingrown toe nail in a pediatric patient named Hannah Greener induced development of atrial fibrillation ensuing in death of the patient. From then on, potential fatal adverse effects of the drugs attracted widespread attention [4]. However, priorly in 1893 Lancet started to record adverse effects of the drugs [5]. In 1906, FDA laid down the rules stating that drugs should be formulated in their pure forms ie. free from other chemical substances. In the year 1936 sulphanimide dissolved in ethylene glycol caused the death of 107 patients. This tragic event led the way to enact pharmacovigilance laws [4]. At the end of 1950s, emergence of cases with phocomelia secondary to thalidomide prescribed as a sedative in pregnant women shocked the whole world. Especially Germany where the drug first marketed was especially affected from harmful effects of the drug, and nearly 10.000 fetuses worldwide were exposed to teratogenic effects of the drug [6]. Though priorly, cases with phocomelia were thought to develop because of environmental teratogens, firstly in 1961 the cases with phocomelia caused by thalidomide were published in Lancet which led to enactment of the drug safety law [7]. Legal regulations known as Kefauer-Harris amendments banned the use of unsafe drugs whatever was their effectiveness would be [6]. These dramatic events experienced related to drug safety emphasized the importance of pharmacovigilance systems and Phase IV studies, and initiated the establishment of pharmacovigilance systems in the whole world [8].

From 2000s on, morbidity, and mortality related to drug use has become the most important health problem in the whole world, and in some developed countries. Besides in some developed countries mortality rates due to unwanted drug reactions have taken the 4th, and 6th place among all-cause deaths which constituted 15-20% of health care expenditures and necessitated establishment of

pharmacovigilance systems [4, 9]. Every year nearly ten thousand people lost their lives because of adverse effects of the drugs, and even with the use of registered drugs unwanted, and unexpected adverse effects can be seen [4].

World Health Organization has pointed out to the differences in diseases seen, and prescription routines among countries. These differences involve a wide spectrum of genetic, dietary, and sociocultural variations. Because of differences in the production, dispensation, and use of drugs, and also herbal medicinal products which can lead to various toxicological problems among countries, each country should establish its unique national pharmacovigilance system [9]. In Turkey, Turkish Drug, and Medical Device Institution of Turkish Republic (TITCK), Ministry of Health, and Social Welfare, and Turkish Pharmacovigilance Center (TÜFAM) enacted a Regulation Regarding the Monitoring and Assessment of Medicinal Products for Human Use. Our national pharmacovigilance system gained a corporate identity [9]. For effective realization of activities of national pharmacovigilance system, as one of the most important point, all health care professionals should be conscious about the fact that pharmacovigilance is a responsibility which should be shared by all health care professionals [4, 5].

Before marketing a drug for the first time, pharmacological properties, and efficacy of the drug are analyzed, and the drug passes through comprehensive, and detailed toxicological, and safety tests. However information about adverse drug reactions can be acquired after postmarketing experience, sophisticated clinical experiments, meta-analyses, and reports of health care professionals about adverse reactions are entered into national, and international databases [9]. As reported in the literature, health care professionals encounter adverse drug reactions at an incidence rate of 1.6-41.4%, and in developed countries, nurses have been playing effective roles in reporting adverse events [10]. Since nurses are the main applicers of human medicinal products in clinics, they are in a position to detect unwanted effects which might develop during the treatment process.

Drug safety are among the priority issues in medicine [11-16]. In developed countries, pharma-

covigilance studies have gained momentum, however in our country only a few studies have pointed out to deficiencies on this issue [17-20]. Ours is a pilot study which was planned with the aim to investigate knowledge, attitude and behaviour of the nurses working in a state hospital about pharmacovigilance, adverse drug reaction and event reporting

MATERIALS AND METHODS

This descriptive, and cross sectional study was performed with nurses working in Kocaeli Gölcük Necati Çelik State Hospital between January, and March 2013. Approval for the study was obtained from the Ethics Committee of Kocaeli University. The objective of the study was explained to 160 nurses, and among them 112 nurses who gave their consent for participation were included in the study. The questions in the survey were prepared based on "Rational Drug Use Questionnaire -2012" forms issued by Ministry of Health, and Welfare.

The following items were investigated in the questionnaire:

- 1. Personal, and professional characteristics** (age, professional seniority, the unit she/he is working)
- 2. What is his/her definition of an adverse effect?** a) life-threatening effect b) fatal side-effect c) any side effect of the drug which prolongs hospital stay or necessitates in-hospital treatment d) any side effect which induces congenital anomalies e) all of them
- 3. How do you react when you encounter an adverse effect?** a) I inform the physician or b) the charge nurse c) I fill up safety assessment or d) adverse effect reporting forms.
- 4. To what authority do you communicate the adverse effects?** a) Chief Physician b) The Directorate of the Hospital c) Quality Management Unit d) Authority in Charge of the Pharmacovigilance.
- 5. To what official organ is notified about your adverse effect report?** a) Provincial Directorate of Health b) Ministry of Health c) TÜFAM.
- 6. What are the minimal adverse effect reporting criteria?** a) Name of the person who reported

TABLE 1. Personal, and professional characteristics of the nurses who participated in the study

	n	%
Age groups		
18-25	6	5.3
26-35	55	49.1
36-50	48	42.8
51-64	3	2.8
Gender		
Female	105	93.7
Male	7	6.3
Educational levels		
Lycée	15	13.4
High school	57	50.9
Faculty	38	33.9
Doctorate/post-graduate	2	1.8
Professional life span		
1-3 years	8	7.1
4-10 years	19	17.0
11-15 years	33	29.5
16-19 years	26	23.2
≥20 years	26	23.2

adverse effect b) The name of the patient who used the drug c) The human medicinal product applied d) Name of at least one adverse effect e) The name of the prescribing physician f) The drugs used by the patient g) All of them

7. Have you ever reported any adverse effect?

For the statistical analysis SPSS 14.0 (Statistical Package for Social Sciences) for Windows 97 program was used. Evaluation of data was performed using descriptive statistical methods. All analyses were evaluated within 95% confidence interval, and using two-way ANOVA test.

RESULTS

Nearly 91.9% of the study participant nurses were in the 26-50 age group. The study population consisted of 93.7% female participants, and 98.2% of them were high school or university graduates. Nearly 75.9% of the survey participants had 10

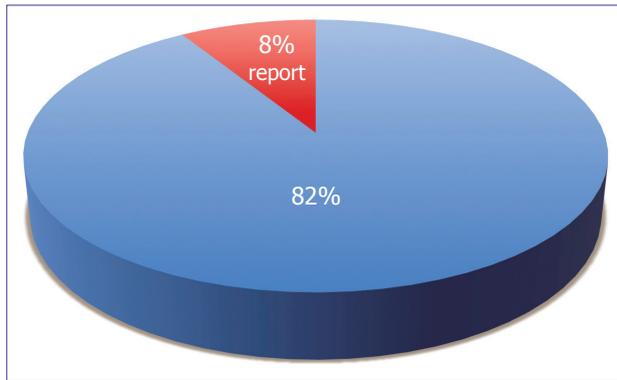


FIGURE 1. ADR reporting rates of the nurses during their professional lives.

or more than 10 years of professional experience. Study participants were outpatient clinic ($n=40$; 35.7%), service (internal medicine, $n=35$; surgical clinics, $n=25$), or charge nurses ($n=12$; 10.7%). Sociodemographic characteristics of the study participants are given in Table 1.

Eighty-three (74.1%) nurses who participated in the survey study accurately defined serious side effect. Most of the (70.5%) participants knew that they should report any unwanted drug effects they observed during their practice. Thirty percent of the participants indicated that they should inform the prescribing physician about the adverse effect, and 39.2% of them knew that they should complete the side effect report form. Half of the participants were knowledgeable about minimum reporting criteria. Although 70.5% of the nurses acknowledged the

necessity of reporting drug adverse effects, only 8% of these nurses reported drug adverse effects during their professional life (Figure 1). The knowledge levels of the participants about pharmacovigilance are given in Table 2.

Thirty-nine (34.9%) participants knew that adverse effect reporting should be addressed to the responsible pharmacovigilance authorities, while 25% of the nurses thought that adverse effects had been communicated to the quality management units. When the knowledge level of the participants about the authorities whom they communicate adverse event reports was inquired, they named City Health Administratives ($n=56$; 50%), Ministry of Health ($n=6$; 5.4%), TÜFAM ($n=9$; 8%), and quality management unit ($n=1$; 0.9%). While 40 (35.7%) participants indicated that they had not known where to address their adverse event reports.

DISCUSSION

Since drug-related mortality rates are quite high worldwide, drug safety is among priorities in medicine [11-16]. Raising awareness about pharmacovigilance, and generalizing adverse effect reporting will not only ensure safe drug use, but also assure determination of specific adverse effects with resultant development of effective treatment modalities [5].

This is a descriptive study investigating awareness, and attitudes of nurses working in the clinics of a state hospital about necessity of ADR reporting. The outcomes of this study have demonstrated that

TABLE 2. The knowledge levels of the participants about pharmacovigilance

	n	%
Number (%) of participants who knew		
The definition of ADR	83	74.1
Necessity of ADR reporting	79	70.5
Necessity for completing ADR report forms	44	39.2
Knowledge level of minimum criteria of reporting	61	50
Number of participants who knew that ADR reports should be communicated		
to the pharmacovigilance regulatory authorities	39	34.9
Number of participant who knew TÜFAM	9	8

despite awareness of ADR reporting was acknowledged, event reporting rates were still relatively low, and authorities to be addressed were not known.

Many investigations have been performed worldwide on the issue of pharmacovigilance, however nowadays the state of pharmacovigilance in our country has been revealed in only limited number of studies [17-20]. As reported in the literature, health professionals encounter adverse drug reactions at incidence rates varying between 1.6, and 41.4 percent [10]. Outcomes of the studies realized on the awareness for pharmacovigilance demonstrate variations among countries [21-24] The necessity of ADR reporting was recognized by different percentages of nurses participating in studies performed in China (1.6%) [22], Nigeria (35%) [23], and India (75%).

Although awareness of pharmacovigilance is improved in developed countries, still importance of educational activities has been emphasized in order to increase event reporting rates [10]. Ekman et al. performed a survey study with nurses in Switzerland, and reported event reporting rate as 14%, while this rate climbed to 30% among those receiving training on pharmacovigilance [21]. In this study, 74.1% of the nurses knew the unfavourable drug reactions, and 70% of them were cognizant that they should report adverse effects. However in their professional past, event reporting rates were found to be relatively lower. In three different studies in our country apart from ours, similar, and lower event reporting rates were indicated [18-20]. Sencan et al. realized a educational, and questionnaire survey study in a private hospital with 15 participants, and found that only 60% of the participant had defined adverse drug reactions correctly [19]. In the study performed by Sencan et al., 60% of the study participants encountered adverse drug reactions in their professional lives, but their event reporting rates were relatively lower [19]. Majority of our study population were of female gender in the 26-50 age group with an educational level of high school, and higher. Besides they had a professional life of at least 10 years, and they were working in services.

In this investigation, though necessity for reporting adverse drug reactions was already acknowledged in 70.1% of the study participants, only 9% of them

reported adverse events. Sencan et al. [19], and Alan et al. [20] indicated incidence of event reporting as, 60, and 65%, respectively. Besides, in our study only 8% of the study participants were aware of the presence of TÜFAM which achieved a corporate identity. Besides only 8% of our study participants were aware of the the presence of TÜFAM which gained its corporate identity in 2005. In a survey study of Alan et al. in Adana region only 1.2% of the participants heard the name of TÜFAM [20]. In another study performed among pharmacists in Istanbul, even though 89 of the pharmacists believed the importance of reporting adverse drug effects, only 7% of them reported adverse effects to TÜFAM [18].

This is a pilot study conducted with the intention to determine awareness of the nurses working in a state hospital about pharmacovigilance so as to shed light on future studies to be performed. Single-centered design of the study precludes making generalizations. According to the results of this investigation, deficiencies in adverse effect reporting, and lack of knowledge about authorities to be addressed implicate that we are still at the bottom of the ladder.

For the establishment of a national pharmacovigilance system, first of all, awareness should be raised among health care professionals about this issue. In our country, drug side effects are not recorded attentively. However, studies on this issue appear to be promising for the future. Further investigations on pharmacovigilance and especially those concerning causes of deficiencies in adverse event reporting should be performed.

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