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The Knowledge and Attitudes of Physicians and Nurses Towards Adverse Event Reporting and the Effect of Pharmacovigilance Training: A Hospital Experience

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Introduction

People are very fortunate today to have modern medicines by which many health conditions are treated. Both prescription and non-prescription medications can treat diseases, reduce symptoms, and enhance patients' health and quality of life. Although, medicines are considered a necessity, taking medication is not always as easy as just swallowing a pill. This is because medicines have some side effects and problems can occur due to a variety of reasons [1,2]. With the use of any drug comes the possibility of unintended consequences which when harmful are referred to as adverse drug reactions (ADRs). These reactions increase morbidity and mortality besides being a financial burden on society [3]. The aim of pharmacovigilance is the detection and assesment of adverse drug reactions (ADR) and pharmacovigilance is defined as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems [4].

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Pharmacovigilance is essential because the clinical information about a medicinal product during the development phase (Phase I-II and III) is usually incomplete on account of a limited number of subjects and the duration of trials. Phase IV of the clinical trial, targeted mainly to the evaluation of a drug, starts when the marketing license is granted and extends over many years. It consists of pharmacoepidemiological studies to evaluate the effectiveness, safety, and utilization of the drug in large populations, under real-life conditions. Pharmacovigilance practices not only help early detection of ADRs, but also facilitate in identifying both risk factors and the mechanism underlying the adverse reactions. At the same time pharmacovigilance can benefit the responsible bodies as they take precautions against future risks of medicinal products that can potentially lead to large costs to society [3,5]. The ultimate objective of ADR reporting is patient safety. Further, objectives are to increase the quality of diagnosis and drug administration, and to procure feedback to both the regulatory authorities and to the pharmaceutical industry [2]. Pharmacovigilance has a growing importance as a science due to the fact that it is changing into a more proactive discipline, and therefore partners of pharmacovigilance have an increasing awareness at several levels of the need to develop practices of ADRs reporting.

The Turkish Ministry of Health established a national pharmacovigilance center, the Turkey Pharmacovigilance Center (TUFAM), following which "Regulation on the Monitorisation and Assessment of the Safety of Medicinal Products for Human Use" was published in the official gazette on 22nd March 2005. This became effective along with "Pharmacovigilance Guidelines for Marketing Authorization Holders of Medicinal Products for Human Use" on the 30th of June 2005 [6,7,8]. As a consequence, all professionals involved in the care of patients, including physicians, dentists, nurses and pharmacists, should report adverse drug reactions related to pharmaceutical treatment. Thorough assesment of these reports should be conducted in order to alert drug safety professionals to new and potentially important information concerning drug associated adverse reactions.

It is crucial to encourage health care providers around the world to report ADRs. For many different reasons (lack of knowledge, lack of awareness of pharmacovigilance systems, heavy work load, hesitation in making the correct desicion), health care professionals do not report as frequently as expected. The aim of this study is to investigate the knowledge and attitudes of health care providers towards and ADR reporting. One of the

other major objectives is to assess the effectiveness of a multidisciplinary collaboration based on an educational pharmacovigilance conference (training meeting) for encouraging spontaneous reporting of ADRs by physicians and nurses in a hospital setting. This setting was chosen due to the fact that there is a greater use of medicinal products and thus occurance of polypharmacy within the hospital environment. The final aim of this study was to analyse the frequency of ADR reporting during hospitalization from physicians and nurses, to identify which drugs are involved in ADRs.

Methods

Study population

The VKF American Hospital is a private hospital with a 300 bed capacity serving 131,000 patients each year. The hospital offers a 24-hours a day diagnostic, inpatient and outpatient care service provided by its 500 physicians.

The present study was designed to reach all of the physicians and nurses employed in the hospital by hospital pharmacists with acedemician pharmacists. After several attempts, it became apparant that was is impractical to bring large numbers of health care providers together. Then the researchers planned to give training sessions on a weekly basis for different departments of the hospital. The meetings were all held early in the morning between 7:00-8:00 am. Researchers conducted 5 different meetings on 5 different days. In more that one month researchers were able to reach 30 participants. A total of 15 physicians and 15 nurses from the hospital attended pharmacovigilance training sessions addressing pharmacovigilance legislation, systems and practical exercises for ADR reporting. The conferences were based on the same educational material, but were organized on different days. Furthermore, two questionnaires were conducted with the physicians and nurses who participated in the meetings, one before, the other after the training session.

Questionnaires

The questionnaires were designed to be short and easy to complete and spread over a total of two pages. The questions in the first questionnaire were answered before the begining of the pharmacovigilance education programme. These questions covered demographic data, including age, sex,

year of graduation, and length of experience as a physician or nurse. In addition, four structured questions were prepared to determine the knowledge of participants about the definition of ADR, along with their experiences of ADR reporting, such as reporting frequency, where they were reported and which classes of drugs were reported. Thus it was planned to evaluate the difference between the knowledge and attitudes of physicians and nurses towards pharmacovigilance. The participants were requested to fill out the second questionnaire immediately after the education session. It consisted of four questions to assess the satisfaction of participants with the conference, their views on the effectiveness of the education, and the recommendations and feedback of those who took part concerning any perceived deficiencies that could be compensated for in future education sessions.

Content of Educational conference slides and folders

A total nmber of 30 physicians and nurses attended the educational programmes mentioned above which lasted about half an hour. A slide show was conducted by the person designated as responsible for pharmacovigilance at the hospital and "Pharmacovigilance Training Folders" were distributed to each participant. Slides and folders were designed to encompass all theoretical aspects as well as necessary practical knowledge in order to facilitate the reporting of ADRs.

One of the aims of the educational sessions was also to provide candidates with in-depth knowledge of terminology because the expressions used to describe adverse events associated with drug use causes much confusion among health professionals.

The educational conference programme was also supposed to provide physicians and nurses important information on how they recognize and report adverse events to the Pharmacovigilance Centre of the hospital in a timely manner.

Four minimum criterias were emphasized as necessary and sufficient in order to report an adverse event [8,9].

- *An Identifiable Reporter*- (Health care Professional e.g. physicians or nurses) Name, address and telephone number if possible so Pharmacovigilance Center can contact if necessary
- *At Least One Suspected Medicinal Product* - Name of drug/product (if possible, tradename and active ingredient)
- *An Adverse Event* - A description with as much information as possible regarding what happened

- *An Identifiable Patient*- (the person experiencing the event) Initials of the patient's name, gender and/or date of birth or age

Moreover, participants of conference were informed about the fact that TUFAM (Turkish Ministiry of Health National Pharmacovigilance Center) requires that the following situations should be also identified and reported as AEs [8,9]:

- Cancer
- Drug abuse and Overdose
- Medication errors
- Potential medication errors
- Matrenal / paternal exposure to a drug prior or after pregnancy
- Usage during breastfeeding
- Lack of effect

Lastly, participants in educational conference were informed about the purpose and legal responsibility of pharmacovigilance practices.

Results

A total number of 30 questionnaires were completed by physicians, 15 were answered before the begining of the pharmacovigilance education programme, and the other half of the questionnaires were completed right after the education session. The overall response rate of physicians to demographic data was 80%. The physicians had a mean age of 43.3 and in accordance with their ages, the graduation year range was mostly between 1990 and 1999 years (40%). In terms of speciality, in this study population, 46.6% of physicians were pediatritians and the others were 3 family physicians (20%), a general surgeon and a physician who had a speciality in emergency service.

The first questionnaire contained four structured questions which are presented in Table I, and in the first question, the physicians were asked to choose the correct definition of 'adverse drug reaction.' The answers were evaluated according to the WHO's definition and of the responding physicians, only 53.3% could match the definition exactly. When the physicians were asked if they had experienced any adverse drug reaction in patients during their career, 100% (n=15) of these physicians answered in the affirmative. While only one physician claimed that

he or she reported these ADRs once or twice a month, approximately 60% of physicians admitted that they reported ADRs rarely. One third (33.3%) of physicians had never reported these ADRs to the concerned organizations, and 46.6% of them admitted that they had not reported ADRs anywhere. The results in table also demonstrate that there were no physicians who reported to TUFAM, while there was a low reporting rate to pharmacist and a little higher reporting rate (20%) to the drug company.

Due to the low reporting rate, 60% of physicians (n=9) did not answer the last question of first questionnaire. Of those able to respond, physicians reported ADRs most frequently for the following classes of drugs: antibiotics (26.6%), analgesics (6.66%), and others including vaccines (6.66%) and baby food (6.66%).

Although the total number of nurses was equal to the total number of physicians, there were meaningful differences in sociodemographic characteristics. There were fourteen female nurses and only one male nurse who participated in pharmacovigilance education conference and they were younger than the physicians with a mean age of 28.6 years. Due to the young profile of nurses, their graduation years were generally between 2000 and 2009 (66.6%), the speciality question was not answered. Compared with physicians, only one nurse did not answer her age and graduation year and this data shows that failure to respond to some questions was lower. Thus, nurses have a greater overall response rate (93.3%) to demographic data.

In the pharmacovigilance education conference, the same questions were prepared for nurses and the answers of the nurses is illustrated in Table II. When nurses were asked to mark the correct definition of 'adverse drug reaction', almost 60% of these nurses answered successfully. Moreover, it was shown that 60% of nurses had experienced adverse drug reactions, but the rest of them had never seen an adverse drug reaction in patients. Like physicians, most nurses (40%) reported ADRs rarely and an equal number of nurses (n=6, 40%) had never submitted these ADRs to the responsible pharmacovigilance centres. On the other hand, while one nurse claimed that she reported ADRs once or twice a week, another claimed that she reported these ADRs once or twice a month. Regrettably, five nurses did not answer question four which asks, 'Where did you report adverse drug reactions?' and four of them (26.6%) reported ADRs nowhere. Thus, similar to physicians, the ADR reporting rate was also found to be low among nurses.

It is seen that 60% of nurses did not answer the last question. Answers in data indicate that nurses mostly reported ADRs for some classes

TABLE I

The attitudes of physicians towards adverse drug reaction (ADR) reporting

Question 1	**Answer**	**Number(n)**	**Percentage(%)**
Which one of the following best describes the 'Adverse Drug Reaction'?	It is an unwanted effect caused by a medicine when used at a normal dose in patients for pharmacological effects.	8	53.30
	It is a noxious and unwanted effect caused by a medicine when used in recommended dosage.	3	20.00
	It is an unwanted effect that occurs during treatment with a medicine and it does not necessarily have a causal relationship with the treatment.	4	26.60
Total		15	100.00
Question 2	**Answer**	**Number(n)**	**Percentage(%)**
Have you ever experienced an adverse drug reaction in your patients during your carreer?	Yes	15	100.00
	No	0	0.00
Total		15	100.00
Question 3	**Answer**	**Number(n)**	**Percentage(%)**
How often do you report Adverse Drug Reactions?	Once or twice a month	1	6.66
	Very rare	9	60.00
	Never	5	33.30
Total		15	100
Question 4	**Answer**	**Number(n)**	**Percentage(%)**
Where do you report adverse drug reactions?	Drug Company	3	20.00
	Pharmacist	2	13.30
	Nowhere	7	46.66
	No answer	3	20.00
Total		15	100.00
Question 5	**Answer**	**Number(n)**	**Percentage(%)**
Which classes of drugs do you frequently report?	Analgesics	1	6.66
	Antibiotics	4	26.60
	Vaccines and baby food	1	6.66
	No answer	9	60.00
Total		15	100.00

TABLE II

The attitudes of nurses towards adverse drug reaction (ADR) reporting

Question 1	**Answer**	**Number(n)**	**Percentage(%)**
Which one of the following best describes the 'Adverse Drug Reaction'?	It is an unwanted effect caused by a medicine when used at a normal dose in patients for pharmacological effects.	9	60.00
	It is a noxious and unwanted effect caused by a medicine when used in recommended dosage.	5	33.30
	It is an unwanted effect that occurs during treatment with a medicine and it does not necessarily have a causal relationship with the treatment.	1	6.66
Total		15	100.00
Question 2	**Answer**	**Number(n)**	**Percentage(%)**
Have you ever experienced an adverse drug reaction in your patients?	Yes	9	60.00
	No	6	40.00
Total		15	100.00
Question 3	**Answer**	**Number(n)**	**Percentage(%)**
How often do you report Adverse Drug Reactions?	Once or twice a week	1	6.66
	Once or twice a month	1	6.66
	Very rarely	6	40.00
	Never	6	40.00
	No answer	1	6.66
Total		15	100.00
Question 4	**Answer**	**Number(n)**	**Percentage(%)**
Where do you report adverse drug reactions?	TUFAM and pharmacist	2	13.30
	Pharmacist	3	20.00
	Nowhere	4	26.60
	Other	1	6.66
	No answer	5	33.30
Total		15	100.00
Question 5	**Answer**	**Number(n)**	**Percentage(%)**
Which classes of drugs do you frequently report?	CNS drugs	1	6.66
	CV drugs	1	6.66
	Oncology drugs	4	26.60
	No answer	9	60.00
Total		15	100.00

of drugs including, 26.6% oncology drugs, 6.66% central nervous system drugs and 6.66% cardiovascular system drugs.

The second questionnaire was in the form of an evaluation and it consisted of an open question and three structured questions which were aimed to assess the contribution of pharmacovigilance education conference to physicians and nurses' knowledge, the usefulness of the presentation and participants' views about whether the rate of ADRs reporting would increase or not. In addition, one last open question was asked to evaluate the deficiencies in the educational sessions according to participants' additional recommendations about pharmacovigilance (Table III).

The overall response rate of physicians to the second questionnaire is 100%. All three structured questions were fully completed and last question was optional, so only four additional recommendations were written by the physicians. 80% (n=12) of physicians claimed that these educational conferences made a big contribution to their knowledge about pharmacovigilance; three of them (%20) believed that the contribution of the conference was minimal. Moreover, nine physicians (%60) stated that the presentation in the conference was very helpful and %40 considered the presentation as somewhat helpful. According to the results of the third question, more than half of the physicians (%60) believed that there will be a big increase in reporting rate and rest of them (%40) considered that the increase will be a little. No one answered these three questions negatively.

In the last open-question, some of the physicians wrote some recommendations and questions which they felt were not adequately addressed in the conference, including, 'What is the difference between the effect of a disease and a drug side effect?', 'Why are the ADRs reports of physicians beneficial?', 'Are the complaints of patients sufficient for reporting or should we find a symptom to report?' and 'Turkish word equivalents to adverse and vigilance should be found and used'. These written questions and comments were considered as deficiences in the conference since the aim was to instantly respond to questions and clarify ambiguous points about pharmacovigilance. In this way, the usefulness of the conferences and rate of ADRs reporting can be raised.

Even though none of nurses answered the last question, three questions were completed after the education sessions. Generally, the results of nurses are similar to the that of of physicians, but the percentage of the first answer is different.

It was observed that while 60% (n=9) of nurses believed that these educational conferences made a big contribution to their knowledge

TABLE III

The evaluation after the pharmacovigilance training conference

		Physicians		Nurses	
Question 1	**Answer**	**Number(n)**	**Percentage(%)**	**Number(n)**	**Percentage(%)**
How do you evaluate the contribution of pharmacovigilance education conference to your pharmacovigilance knowledge?	A big contribution	12	80.00	9	60.00
	A little contribution	3	20.00	6	40.00
	No contribution	0	0.00	0	0.00
Total		15	100.00	15	100.00
Question 2	**Answer**	**Number(n)**	**Percentage(%)**	**Number(n)**	**Percentage(%)**
How do you consider the helpfulness of presentaion?	Very helpful	9	60.00	9	60.00
	Somewhat helpful	6	40.00	6	40.00
	Not helpful	0	0.00	0	0.00
Total		15	100.00	15	100.00
Question 3	**Answer**	**Number(n)**	**Percentage(%)**	**Number(n)**	**Percentage(%)**
Do you consider the rate of adverse drug reporting to Pharmacovigilance Centre will increase by this conference?	A lot increase	9	60.00	9	60.00
	A little increase	6	40.00	6	40.00
	No increase	0	0.00	0	0.00
Total		15	100.00	15	100.00
Question 4					
Please write any additional recommendations (not mentioned in conference) about pharmacovigilance?		What is the difference between effect of disease and side effect?		No additional recommendations from nurses	
		Why are the ADRs reports of physicians beneficial?			
		Are the complaints of patients sufficient for reporting or should we find a symptom to report ?			
		Turkish word equivalents to adverse and vigilance should be found and used			

about pharmacovigilance, six of them (%40) evaluated the contribution of conference as "little". Like physicians, the evaluation of the nurses about education was not negative and nine nurses (%60) claimed that the conderence presentation was very helpful. In addition, the same number (n=9) of nurses (%60) believed that there will be a big increase in reporting rate thanks to these conferences. Finally, nurses did not write anything in response to the last open-question. However, the oral questions of nurses were responded to, and any ambiguities arising from the presentation were clarified face to face at the end of conference.

Discussion

The results of the present study firstly demonstrate that the physicians and nurses in this private hospital have insufficient knowledge about pharmacovigilance and ADRs reporting. However, the main limitations of the study were the very low number of participants (n=30), the poor response rate and the lack of response to some questions. The low participation in the study and the failure to respond to some questions may be a consequence of poor attitudes and behaviors of physicians and nurses towards pharmacovigilance activities. On the other hand, this is a study of a single district and does not have a claim to present all the physicians and nurses in Istanbul.

According to the results, nurses chose the definition of 'adverse drug reaction ' correctly with higher rate of 6.7% when compared with physicians. No significant reason of this difference was found between the groups for the definition of ADR. However, the percentage of physicians (100%) who had experienced any adverse drug reaction in patients during their career was significantly greater than the percentage of nurses (60%). The difference may indicate poor knowledge and awareness of ADRs by nurses; the younger profile of the nurses may be another reason for poor experience of identifying ADRs in patients. Moreover, the lower percentage may be due to the fact that patients generally tell their complaints to physicians rather than to the nurses. However, nurses are close to the patients and in a position to detect possible ADRs, so this reason is can not be considered an adequate explanation. Education encouraging nurses to identify ADRs will be an effective method of improving detection and ensuring the accurate diagnosis of adverse drug reactions.

Even though, all physcians and more than half the nurses had experienced adverse drug reaction in their patients, the ADR reporting rate was also found to be quite low. By interpreting the results, the low rate

of ADR reporting may indicate the poor knowledge of participants about reporting procedures and requirements. In other words, there was no significant difference between the groups in reporting behavior, which may be due to the lack of tradition or habit. In spite of lower experience rate of nurses, the comparison between the physicians and nurses showed that the nurses who report ADRs frequently had a higher percentage than physicians, which suggests that nurses play a valuable part in improving pharmacovigilance. Nurses, through their close contact with the patients, are well placed to be a key source of information on ADRs.

Furthermore, data indicate that the number of nurses who did not answer the question or admitted that they did not report ADRs anywhere was not significantly different from the number of physicians. However, there were more nurses who reported ADRs to pharmacists, and while there were some nurses who admitted to reporting ADRs to the national pharmacovigilance center (TUFAM), there were no physician who reported to TUFAM. In partıcular, the very low reporting rate of physicians to the national pharmacovigilance center and the correspondingly high reporting rate to the pharmaceutical industry may be indicative of an even lower level of pharmacovigilance awareness in the studied participants, and the results of this question also show that, physicians are more in contact with marketing authorisation holders.

The results of the present study indicate that knowledge and attitudes exert a strong influence on ADR reporting. Fortunately, attitudes are potentially modifiable variables and the degree to which physicians and nurses are informed about the principles of pharmacovigilance and their practice of these principles has a large impact on ADRs reporting. Therefore, pharmacovigilance education conferences should be conducted to inform all health care providers about the full implementation of all the requirements and functioning of the pharmacovigilance systems.

The results of the second questionnaire which was conducted right after the conference, demonstrate that these educational sessions can significantly modify participants' reporting-related attitudes and influence the ADR reporting behavior in a positive manner. There were no significant differences between physicians and nurses in terms of response, but the proportion of physicians who believed that these educational conferences made a big contribution to their knowledge was 20% more than that of the nurses. In addition, in this study, attitudes towards spontaneous reporting of ADRs showed that when deciding whether to report or not, physicians were influenced by the knowledge that the reaction was considered "well known" or "not important". However, all adverse

events regardless of causality assessment, need to be reported because it is not always possible, without further investigation, to know whether the adverse event was due to a drug or not.

This study has also found that physicians and nurses generally tend to report more serious adverse events, but health providers are encouraged to record and report all adverse events of marketed drugs, whether or not they are suspected of being serious. Moreover, the questions raised in the educational conferences highlight some important issues. One is these issues concerns the question of whether a complaint or a symptom experienced by a patient is sufficient for spontaneous reporting, because the spontaneous ADR reporting system is still the basic component for the comprehensive post-marketing surveillance of drug-induced risk.

Finally, after the pharmacovigilance education conferences, it seems that physicians and nurses have sufficiently understood their pivotal role in the surveillance of the safe use of medicines and they have also understood that all the members of the health team share the responsibility for pharmacovigilance practices. In other words, pharmacovigilance is a shared responsibility of all health care professionals and only good cooperation between partners can help to extend and enhance human life.

In conclusion, to achieve future goals, all hospital pharmacists should be trusted and encouraged to take increased responsibilities in "pharmacovigilance system building" activities even if they do not provide a formal hospital pharmacovigilance contact point service. All hospital pharmacists whether or not they have had training in clinical pharmacy, have a responsibility for ADRs and pharmacovigilance.

Summary

Aim: To investigate the knowledge and attitudes of the Turkish community physicians and nurses towards pharmacovigilance and adverse drug reactions (ADR) reporting before and after a pharmacovigilance training session is conducted, to assess the effectiveness of a multidisciplinary collaboration based on an educational pharmacovigilance conference for improving spontaneous reporting of ADRs by physicians and nurses in a hospital setting.

Setting: The study was carried out in the Vehbi Koç Foundation (VKF) American Hospital which is the one of the private hospitals in Istanbul and continues to develop and gives the best quality of services within each specialty of modern medicine.

Methods: A total of 15 number of physicians and 15 number of nurses from hospital attended the pharmacovigilance conferences. A slide show was conducted and folders were distributed to each physician and nurse. Slides and folders have been targeted to encompass all theoretical aspects and necessary knowledge about pharmacovigilance in order to help report ADRs. Additionally, two questionnaires were conducted with participants. First questionnaires, were answered before the begining of conferences, contained demographic data and other four structured questions to determine the knowledge of participants about the definition of ADR plus the experiences with ADRs reporting such as reporting frequency, where they were reported and which classes of drugs were reported. The second questionnaires, were filled right after the education session, consisted of four questions to assess the satisfaction of participants about conference, the efficiency of education and the missing points that can be added to education sessions based on the participants' recommendations and feedbacks.

Results: While there were meaningful differences between physicians and nurses in sociodemographic characteristics, there was no significant difference in responds of first questionnaire. Of the responding participants, only 53.3% of physicians and almost 60% of nurses mark the correct definition of 'adverse drug reaction'. It was shown that all physicians (100%) and most of nurses (%60) had experienced adverse drug reactions during their career, but some of them reported seen ADRs rarely and unfortunately, others had never reported. On the other hand, the comparision between physicians and nurses showed important differences in terms of classes of drugs that cause ADR reporting. Among the ADR reports of physicians, antibiotics were the most frequent, but nurses claimed that they mostly reported ADRs for oncology drugs.

Conclusion: Due to the pharmacovigilance education conferences in VKF American Hospital, physicians and nurses clarified their role and increased their knowledge about the reporting requirements and positive attitude, and also resulted in that some of the participants increased reporting ADRs after these conferences. To create a 'reporting culture' new educational conferences are necessary for health care professionals to increase their involvement in the system and the pharmacists should always be trusted and encouraged to inform health care professionals about principles of pharmacovigilance.

Key words: Harmacovigilance, Pharmaceutical services, ADR reporting.

Özet

Farmakovijilans Eğitiminin Hekim ve Hemşirelerin Advers İlaç Reaksiyonu Bildirimi hakkındaki Bilgi ve Tutumları Üzerine Etkisi: Bir Özel Hastane Eczanesi Deneyimi

*Amaç:*Bu çalışmanın amacı Türk doktor ve hemşirelerin farmakovijilans ile ilgili farkındalıklarını ölçmek ve verilecek bir seminerin onların Advers İlaç Reaksiyonları (ADR) raporlaması ile ilgili algımaları ve tutumları üzerindeki etkisini incelemektir. Aynı zamanda, demografik ve profesyonel kriterlere göre oluşturulan gruplar arasındaki farklılıklar anlaşılmaya çalışılmıştır.

Çalışma Alanı: Bu çalışma, İstanbul'da bulunan özel hastaneler içerisinde sürekli gelişen ve kabul edilebilir kalitede hizmet veren VKV (Vehbi Koç Vakfı) Amerikan Hastanesi'nde gerçekleştirilmiştir.

Metot: 15'i hekim ve 15'i hemşire olmak üzere toplam 30 kişiye eğitim verilmiştir. Katılımcılara görseller eşiliğinde bir farmakovijilans ve ADR raporlama eğitimi verilmiş ve seminer (eğitim) öncesinde ve sonrasında iki anket doldurmaları istenmiştir. Seminerlerde katlımcılara farmakovijilans ile ilgili teorik çerçeve ve gerekli bilgiler verilmesi hedeflenmiştir. Seminer öncesi verilen ilk anket katılımcıların demografik bilgilerini elde etmeyi, onların ADR ile ilgili bilgi ve tecrübelerini ölçmeyi amaçlamaktadır. Seminerden sonra verilen ikinci anket ise katılımcıların memnuniyetini ölçerek seminerin etkisini değerlendirmeyi ve katılımcıların önerilerini öğrenmeyi amaçlamıştır.

Bulgular: Hekim ve hemşirelerin, sosyodemografik özellikler arasında farklılık olsa da, advers ilaç reaksiyonu doğru tanımı konusunda hiçbir farklılık görülmemiştir. Doktorların sadece %53.3, hemşirelerin ise sadece %60'ı ADR tanımını doğru olarak bilmiştir. Doktorların hepsi (%100) ve hemşilerin %60'ı daha önce bir ADR'a şahit olduklarını ifade etmiştir. Buna karşın, doktorların %46.6'sı ve hemşirelerin %40'ı daha önce hiç ADR raporlamadıklarını ifade etmişlerdir. Tüm katılımcıların sadece %45.%'i doğru kurumlara raporlama yapmıştır. Sonuç olarak eksiksiz cevap veren katılımcıların sadece %36.3'ü ADR'ın tanımını doğru bilip, bir ADR'a şahit olmuş ve bunu doğru bir kuruma raporlamıştır. Hekimler en çok antibiyotiklerde advers ilaç reaksiyonları ile karşılaştıklarını bildirirken, hemşireler için onkoloji ilaçları ön sırada yer almaktadır.

Sonuç: Bulgular göstermiştir ki, katılımcılar farmakovijilans'ın önemi konusunda yeterince bilgiye ve farkındalığa sahip değildir. İkinci anketin bulgularına göre bu sorun sürekli yinelenen ve yenilenen seminerlerle çözülebilecektir. Hastane eczacıları, beraber çalıştıkları sağlık mesleği mensuplarını farmakovijilans sistemine daha çok entegre edecek tüm çalışmalarda yer almalı ve bu şekilde "bildirim kültürü"nün artmasına katkı sağlamalıdır.

Anahtar Kelimeler: Farmakovijilans, Eczacılık Hizmetleri, Advers İlaç Reaksiyonu Bildimi

REFERENCES

1. Belton K. J.: Attitude survey of adverse drug-reaction reporting by health care professionals across the European Union, Eur J Clin Pharmacol, 52: 423-427, 1997.
2. Ulfvarson J. RN, PhD, Mejyr S. RN, Bergman U. MD, PhD, Nurses are increasingly involved in pharmacovigilance in Sweden, pharmacoepidemiology and drug safety, 16: 532–537, 2007. Published online 30 October 2006 in Wiley InterScience www.interscience.wiley.com
3. Rehan HS, et al.: Physician's guide to pharmacovigilance: Terminology and causality assessment, Eur J Intern Med, doi:10.1016/ j.ejim.2008.04.019, 2007.
4. Toklu H Z, Keyer Uysal M.: The knowledge and attitude of the Turkish community pharmacists toward pharmacovigilance in the Kadikoy district of İstanbul, Springer Science+Business Media B.V., doi 10.1007/s11096-008-9209-4, 2008.
5. Pedro´s C, Vallano A, Cereza G, Mendoza-Aran G, Agustı´ A, Aguilera C, Dane´s I, Vidal X, Arnau J. M. : An Intervention to improve spontaneous adverse drug reaction reporting by hospital physicians, a time series analysis in Spain, Drug Safety, 32 (1): 77-83, 2009.
6. Aydınkarahaliloğlu D.: Pharmacovigilance System in Turkey, Turkish Pharmacovigilance Center (TUFAM), EMEA European Medicines Agency, 2007. http://www.emea.europa.eu/pdfs/euenlargement/turkey/turkeyppt/aydinkarahaliloglu
7. WHO. Pharmacovigilance: The importance of pharmacovigilance - safety monitoring of medicinal products, Geneva, Switzerland; 2002. http://apps.who.int/medicinedocs/en/d/Js4893e/3.html#Js4893e.3
8. Beşeri Tıbbi Ürünlerin Güvenliğinin İzlenmesi ve Değerlendirilmesi Hakkında Yönetmelik (22 Mart 2005 tarihli ve 25763 sayılı Resmi Gazete, yürürlüğe giriş tarihi: 30/06/2005) [Guide for the monitorization and evaluation of the medicinal products.] Published in the official gazette in 30th March 2005 to become valid by 30th June 2005]. http://rega.basbakanlik.gov.tr/.
9. Pharmacovigilance Broshure of Bristol-Myers Squibb Company, Prepared in August 2008, Emel M. Ceyhan BMS / TR – Pharmacovigilance/Medical Department.