**Name of Journal:** *World Journal of Clinical Cases*

**Manuscript NO:** 84035

**Manuscript Type:** ORIGINAL ARTICLE

***Prospective Study***

**Defining the awareness and attitude of the clinicians through pharmacovigilance in Turkey**

Aydin OC *et al*. Clinicians and pharmacovigilance

OzlemCelik Aydin, Sonay Aydin, Hakkı Zafer Guney

**OzlemCelik Aydin, Sonay Aydin, Hakkı Zafer Guney,** Department of Medical Pharmacology, Gazi University Faculty of Medicine, Ankara 06500, Turkey

**Author contributions:** Aydin OC and Guney HZ put forward the concept; Aydin OC was responsible for designing; Guney HZ were responsible for supervision; Aydin S, Aydin OC and Guney HZ did the literature search and reviewed the manuscript critically; Aydin S and Aydin OC were responsible for materials and wrote the manuscript; All authors have read and approved the final manuscript.

**Corresponding author: OzlemCelik Aydin, MD, Doctor,** Department of Medical Pharmacology, Gazi University Faculty of Medicine, Besevler, Ankara 06500, Turkey. ozlemclk\_89@hotmail.com

**Received:** February 21, 2023

**Revised:** May 1, 2023

**Accepted:** June 9, 2023

**Published online:**

**Abstract**

BACKGROUND

Pharmacovigilance (PV) is the activities and scientific studies conducted to detect, evaluate, understand or prevent adverse reactions and other drug-related problems.

AIM

To define the awareness and experiences of the clinicians on PV and adverse drug reactions (ADRs) in Turkey.

METHODS

The study was cross-sectional and analytical. Data were obtained through a questionnaire. The questionnaire was sent *via* e-mail. The survey was sent to 2030 physicians and 670 participated.

RESULTS

The most appropriate definition of PV was correctly defined by 53.9% of the participants. The most important goal of PV was correctly defined by 54.9% of the participants, and 27.3% of the participants were aware of the Turkish Pharmacovigilance Center. Nonsurgical physicians had better PV knowledge than surgical physicians. A total of 80.9% of the physicians who encountered ADRs, filled in the ADR notification form, and 8.8% received training on how to fill in the form. PV knowledge of the clinicians was not sufficient. Although half of the physicians encountered ADRs, the rates of seeing and filling in the ADR form were low.

CONCLUSION

Few of the physicians followed the current information about PV. The results provide more comprehensive data on PV practices and ADR reporting at a national level.

**Key Words:** Pharmacovigilance; Physicians; Knowledge level; Attitude; Behavior; Adverse drug reaction

Aydin OC, Aydin S, Guney HZ. Defining the awareness and attitude of the clinicians through pharmacovigilance in Turkey. *World J Clin Cases* 2023; In press

**Core tip:** Pharmacovigilance (PV) is the activities and scientific studies conducted to detect, evaluate, understand or prevent adverse reactions and other drug-related problems. This study define the awareness and experiences of clinicians about PV and adverse drug reactions (ADRs) in Turkey. PV knowledge level of the physicians was not sufficient. The results provide more comprehensive data on PV practices and ADR reporting at a national level.

**INTRODUCTION**

Pharmacovigilance (PV) is the activities and scientific studies conducted to detect, evaluate, understand or prevent adverse reactions and other drug-related problems[1,2]. Before a drug is licenced, its safety and efficacy are assessed in a small number of people. Hence, the safety profile is better established with extended use in a wider population following registration. It is also possible for previously unidentified adverse drug reactions (ADRs) to occur throughout this process[3]. After the dramatic withdrawal of numerous medications from the market as a result of ADRs observed after registration, PV systems were implemented globally[4].

In Turkey, the Turkish Pharmacovigilance Center (TUFAM) is responsible for collecting, recording, analysing, and reporting ADRs to the World Health Organization National Monitoring database. Adverse effect reporting forms are used by healthcare professionals to report suspected adverse reactions to TUFAM. Healthcare professionals can report directly to TUFAM or through PV contact points responsible for hospitals[5].

Each healthcare professional must carefully examine PV because of their shared responsibility for PV applications. The knowledge, attitudes, and behaviours of healthcare personnel regarding PV can have a direct impact on patient safety. There is research analysing the PV knowledge of healthcare workers in Turkey and around the world. In research comparing physicians’ knowledge and attitudes on rational drug use and PV at a Turkish hospital, 60.6% of physicians did not report ADRs, 44% were aware of PV, and 70.3% were unaware of TUFAM. In this study, it was determined that there was not enough awareness among physicians regarding ADR reporting and PV. However, the fact that it was a study conducted in a single province and in a single hospital was one of the limitations of the study[6]. In a comparable study including physicians and nurses working in a tertiary hospital in Turkey, it was determined that neither group had sufficient expertise to fulfil their PV responsibilities. In addition, it was noted that neither group sufficiently documented ADRs[7].

The purpose of this study was to administer a questionnaire designed to assess the knowledge, experience and perspectives of clinicians on PV and reporting ADRs in as many institutions as feasible. The acquired data will be used to identify any flaws of physicians in the field of PV, improve the current situation, and provide a base for future research in this area.

**MATERIALS AND METHODS**

This cross-sectional analytical investigation was approved by the local ethics committee.

Six hundred participants were determined to be necessary for a meaningful analysis based on a power analysis with a rate of 0.05 for type 1 error and 0.8 for type 2 with a 95% confidence interval. There was no time limit for completing the questionnaire.

The study included everyone who agreed to participate in the survey. The questionnaire was distributed to a total of 2030 physicians, 670 of them responded, and 43 were excluded since they did not complete the questionnaire. Finally, the study population consisted of 627 participants.

The questionnaire consisted of four sections that enquired about sociodemographic variables, level of PV knowledge, attitudes towards PV, and PV-related behaviours. The questionnaire is shown in Supplementary Material. The questionnaire was distributed to physicians using e-mail gathered from the websites of their institutions.

SPSS for Windows version 20 (IBM SPSS Inc., Chicago, IL, United States) was used to evaluate the data. The normal distribution of the data was analysed with the Kolmogorov–Smirnov test. Numerical variables were expressed as percentages. Since the majority of variables lacked a normal distribution, nonparametric tests were utilised in the study. The Kruskal–Wallis test was utilised to compare various independent groups, while the Mann–Whitney *U* test served as the *post hoc* analysis. The *P* value to be used for *post hoc* analysis was calculated *via* Bonferroni correction. The *χ*2 test was used to analyse the variation in categorical data between groups.

*P* < 0.05 was established as the threshold value for statistical significance.

**RESULTS**

The questionnaire was distributed to a total of 2030 physicians, 670 of them responded, and 43 were excluded since they did not complete the questionnaire. The study population consisted of 627 participants from 38 different cities. The participation percentage for the survey was 30.8%. Based on the collected data, it was determined that the average time required to complete the questionnaire was 7.6 (6–9) min.

Three hundred and fifty-nine (57.3%) of the respondents were female and 268 (47.7%) were male. The distribution of the participants by age groups is presented in Table 1. The largest number of participants was from internal medicine (*n* = 85; 13.6%). Four hundred and forty-nine participants were nonsurgical physicians and 178 were surgeons (Table 2). Professional experience of 245 (39.1%) participants was 5–9 years (Table 3).

The best definition of PV was known correctly by 338 (53.9%) of the participants. Three hundred and forty-four (54.9%) participants correctly identified the most significant objective of PV. One hundred and seventy-one individuals (27.3%) indicated that they were aware of TUFAM. The institution responsible for monitoring ADRs in Turkey was correctly identified as TUFAM by 330 (52.6%) participants. The correct response rate was significantly higher in nonsurgical physicians than in surgeons (255/449, 56.7% *vs* 75/176, 42.6%: *P* = 0.01). One hundred and thirty-three of 171 (77.7%) of the physicians who previously stated that they were familiar with TUFAM were able to identify TUFAM correctly, when they were questioned about the institution responsible for monitoring ADRs in Turkey. When the physicians’ awareness of the PV contact points (PCPs) in the hospitals was questioned, only 88 (14%) were aware of the PCPs and 395 (63%) were not. In addition, 144 physicians (23%) reported that they had no idea about PCPs. Awareness of PCPs was significantly higher in nonsurgical physicians than in surgeons (74/449, 16.4% *vs* 14/178, 9.5%: *P* = 0.005). Five hundred and forty-six (87.1%) of the physicians who participated in the survey thought that ADR notifications were necessary. According to the Turkish regulations published on PV, the healthcare professionals responsible for reporting ADRs in a healthcare institution were known to be correct (doctor, nurse, pharmacist, dentist, and midwife) by 109 (17.4%) of the participants. The number of physicians who knew the criteria for severe ADR was 335 (53.4%). The rate of knowing the criteria for severe ADRs was significantly higher in nonsurgical physicians compared with surgeons (263/449, 58.5% *vs* 72/178, 40.4: *P* = 0.001). Sixty-seven (10.6%) of the participating physicians correctly answered the number of days within which ADRs must be notified (15 d). Compared with surgeons, this percentage was greater among nonsurgical physicians (9/178, 5% *vs* 55/449, 12.2%: *P* = 0.007). The minimum data required for proper reporting of suspected ADRs were accurate for 323 participants (51.5%). The level of knowledge about PV was generally better in nonsurgical physicians.

Four hundred and seventeen (66.5%) of the participating physicians believed that reporting ADRs was a professional obligation. This ratio was significantly higher in nonsurgical physicians than in surgeons (316/449, 70%, 3 *vs* 101/178, 56%, 7: *P* = 0.001).

One hundred and twenty (19.1%) of the participants answered correctly when asked what should be done in the event of suspected ADRs (the drug should be discontinued and/or substituted, and ADRs should be documented). Four hundred and seventy-nine (76.3%) of the participating physicians believed that PV should be taught in depth to healthcare workers.

Participants were asked what prevented them from submitting an ADR notification: 35 physicians (5.5%) said that none of the identified factors would deter them from reporting. The most common reason for not reporting ADRs was that it was difficult to determine whether they had occurred (320/592, 54%). Table 4 displays other reported causes and their incidence.

Three hundred and fifteen participants (50.2%) reported having previously encountered ADRs. Nonsurgical physicians were more likely to experience ADRs (237/449, 52.7% *vs* 78/178 43.8%: *P* = 0.04). One hundred and seventeen (18.7%) of the physicians were familiar with the ADR reporting form. Nonsurgical physicians were more likely than surgeons to encounter the ADR notification form (102/449, 22.7% *vs* 15/178, 8.4%: *P* = 0.001). Five hundred and thirty-nine (86%) of the participants had never filled out a form to report ADRs, which was more common among surgeons (376/449, 83.7% *vs* 163/178, 91.5%: *P* = 0.01).

Among the physicians who believed that reporting ADRs was a professional requirement and who had already experienced ADRs, 189 (77.8%) had submitted an ADR notification form previously. Fifty-five (8.8%) of the participating physicians received training on how to complete the ADR notification form. The rate of educational attainment among nonsurgical physicians was considerably higher than among surgeons (49/449, 10.9% *vs* 6/178, 3.3%; *P* = 0.003).

There is a resource that can assist physicians in completing the ADR notification form, according to 91 physicians (14.5%). Forty-seven (7.5%) physicians stated that the relevant PCP notified them of the procedure for reporting ADRs. Ten physicians (1.6%) said they constantly followed the latest discoveries in PV, whereas 355 physicians (56.6%) said they never did.

**DISCUSSION**

This study aimed to investigate the level of clinicians’ knowledge, attitudes and actions towards PV and obtain information on future PV research. According to the results, 53.9% of the participants properly identified the best definition of PV, 54.9% correctly identified the most significant goal of PV, and 27.3% were aware of TUFAM. Nonsurgical physicians were more knowledgeable about PV than surgeons were, and 8.8% of the participants received training on how to complete the ADR notification form.

In two prior investigations conducted in Turkey, the percentage of physicians who correctly identified the most accurate definition of PV was 44% and 62.1%, respectively, similar to this study[6,7]. Due to the fact that our study included physicians from several hospitals, it has the potential to provide more comprehensive and accurate data than past studies. The general low incidence is attributable to the lack of education.

In one study conducted in Northern Cyprus, 19.7% of physicians correctly defined PV[8]; however, in another study conducted in Kuwait, 74.4% of physicians correctly defined PV[9]. In an Italian study of paediatricians, 78% of the participants correctly defined PV[10]. Yet, the level of professional experience of the participating physicians in that study was greater than in our study, and our study included physicians from several specialties. This may be a contributing factor, as well as the fact that the degree of medical knowledge in Italy is higher. While physicians in Turkey and worldwide hade insufficient knowledge to define PV, European physicians appeared to have a lower level of inadequacy. This deficiency can be remedied by increasing the number of national and hospital-level PV promotion initiatives for physicians.

The percentage of participants who correctly identified the most essential function of PV was 61.7% in a single hospital study conducted in Turkey[7]. According to the Kuwaiti survey, this rate was 68.5%[9]. Our data, previous national data and international data are mostly comparable and all of the results indicate the need for a detailed education programme.

The proportion of respondents who indicated that they were familiar with TUFAM was 25% and 26.6% in two distinct investigations conducted in a single hospital in Turkey[6,7]. The outcomes are comparable with our study. Nonetheless, the involvement of physicians from various hospitals and cities in our study and the size of our sample were advantageous characteristics. In addition, in a survey involving radiologists in Turkey, 19.8% of the participants were found to be aware of TUFAM[11].

While 27.3% of the participants were aware of TUFAM, 52.6% of the participants correctly identified TUFAM as the institution responsible for monitoring ADRs in Turkey. This demonstrated that some participants accurately identified the organisation responsible for ADR monitoring based on guess rather than information. As additional evidence supporting this conclusion, about one-third of the participants who claimed to be familiar with TUFAM were unable to identify the entity responsible for monitoring ADRs when asked about TUFAM. The results indicated that physicians were unaware of the function and purpose of TUFAM and that there was minimal demand for training on this topic.

In two separate investigations including Turkish physicians from the same hospital, the rate of the physicians familiar with the PV contact points was 24.4% and 31%[7,12]. In a study from a single centre in Uganda, this rate was 21.5%[13]. We observed that as the number of participants and centres increases, awareness appears to decline. In a study involving only radiologists in Turkey, only 5.9% of the participants knew about PCPs at their institution[11]. In summary, we may conclude that hospitals do not promote PCPs and physicians are not well informed about this topic.

The proportion of physicians who thought that ADR notifications were necessary was 91% and 93% in two different studies from Turkey, which is similar to our results[7]. In a study conducted in Northern Cyprus, 56% of participating physicians believed that ADR reporting was required[8]. This was almost 97 in studies conducted in Kuwait and India[14,15]. The data from Turkey and Northern Cyprus lag behind those from other countries. This suggests that awareness of ADR notification should be improved.

According to the Turkish PV regulation, the rate of awareness among healthcare professionals responsible for reporting ADRs in a healthcare institution is low. Consistent with the literature, the most common correct answer is physician and the rarest is midwife. This demonstrates that physicians are aware of their requirements for ADR notification, but other healthcare workers are less aware of their obligations in this regard.

With the ADR notification form, the severity criteria of ADRs are requested. Thus, physicians should be aware of this. Although the rate of accurate identification of serious ADRs is low, it is approximately four times greater than the rate for physicians who previously submitted an ADR notification form. This gives rise to the notion that learning serious ADRs requires both theoretical knowledge and form-filling experience. This ultimately underscores the significance of PV training. In a comparable study conducted in Turkey, the most frequently picked criteria for severe ADR were life-threatening and mortality, while the least frequently selected criteria were prolongation of hospitalisation and duration of stay[7]. The least-selected criterion in our study was hospitalisation and length of stay. In a survey study involving radiologists in Turkey, 85.1% of participants were able to define serious ADRs[11].

In this study, 10.6% of physicians accurately estimated the number of days within which ADRs should be reported. According to a Turkish study, this was 15%[7]. The disparity in rates may be attributable to the difference in sample size and the participation of physicians from various hospitals in our study.

The most important criterion in the correct reporting of an ADR is knowing the minimum requirements for reporting. For this reason, the mentioned data are critical for a healthy reporting process. There was no study among physicians that questioned the minimum data required for proper reporting of suspected ADRs, and a study among nurses yielded results comparable to ours.

In a study conducted in Turkey, 95.3% of physicians believed that it was their responsibility to report ADRs[7]. In a comparable study conducted on Turkish nurses, this rate was 81.7%[16]. In a study in Northern Cyprus, 30.8% of participating physicians reported that it was their responsibility to report ADRs[8]. In a study in Pakistan, 73% of physicians stated that reporting ADRs was their responsibility[17]. Compared with previous research, the rate obtained in our study was notably low. Nonetheless, the rate was greater than in Northern Cyprus. The population sizes of the cited studies were significantly smaller than in our study. In addition, the range of participants’ professional experience was more restricted than in our study. They are believed to be the primary causes of the aforementioned disparity.

When questioning what to do in case of suspected ADRs, the most frequently stated reasons in the literature, similar to our study, were that ADRs should be reported and the drug discontinued[7].

According to a survey conducted in Turkey, 87.6% of nurses believed that PV should be taught in depth to healthcare practitioners[16]. Our study included physicians. The greater rate among nurses may be attributable to the fact that the aforementioned study was conducted in a single institution, or to the fact that nurses were more aware of this issue.

The number of physicians who reported prior experience of an ADR was higher in nonsurgical physicians than in surgeons. Since nonsurgical physicians prescribe more drugs to patients, it was expected that the rate would be greater. In a study performed in Turkey, 51% of physicians reported weekly encounters with 1–5 ADRs[7].

According to a Turkish study, 59.9% of physicians had previously seen an ADR reporting form[6]. The rate in our study was lower. This may be because we included physicians from various cities and hospitals.

The percentage of participants who completed the ADR reporting form was 8% and 13.3% in two Turkish investigations involving physicians from the same institution[6,7]. In our study, this rate was similar to 13.3%. However, in light of the fact that 50.2% of physicians who participated in our study had previously encountered ADRs, the rate was low. There are numerous reasons why clinicians do not report ADRs. In our survey, the most frequent response to the issue of what will discourage you from reporting ADR was because it was difficult to determine whether or not ADRs occurred. In another study conducted in Turkey, lack of knowledge of the national PV system was cited as the leading cause[18]. We might have cited complexity of the ADR notification form as one of the reasons for abandoning ADR reporting. This could also be a reason for physicians. In an upcoming study of a comparable nature, it would be prudent to investigate this explanation. When the data are considered, it is evident that physicians should be encouraged to report ADRs and that their knowledge should be improved.

According to a study conducted in Germany, 10.8% of physicians did not report any ADRs[19]. According to a study conducted in Cyprus, 47.6% of physicians did not disclose the ADRs that they observed[20]. Compared to Turkey, the reporting rates are considerably higher. This suggests that physicians in Germany and Cyprus are more aware of PV and under-report fewer ADRs.

To the question of which reason would discourage reporting ADRs, German physicians cited not reporting previously known ADRs and not having enough time to report[21]. In Saudi Arabia, the most common reasons were not knowing how to report ADRs (43.8%) and not believing that ADRs were important (17.5%)[18]. In a Kuwaiti study, the most common reason for physicians was not knowing how to report ADRs[9].

Some suggestions can be made to increase ADR reporting rates. New regulations regarding the reasons for under-reporting ADRs by physicians are required, as are modifications to make reporting simpler and more attractive for physicians. Increasing physicians’ access to forms can be accomplished by making forms widely available in outpatient clinics and clinical departments of hospitals. By integrating a simple program into the hospital’s system, it is possible to ensure that physicians report patient-related information to the PCP or directly to TUFAM. The rate of report completion by physicians can be increased by making the ADR reporting form as simple as possible and highlighting the minimum criteria. Consequently, the quality of the documents to be evaluated will improve. TUFAM can provide direct feedback to the reporting physicians. Again, a document comparable to a letter of appreciation can be presented to the physicians who notified the hospital. Thus, the significance of informing physicians will become apparent. Presentations and sessions can be organized to raise physicians’ awareness of PV and ADR reporting at scientific conferences and meetings.

According to a study conducted with nurses in Turkey, 31% received training on this topic[16]. In a similar survey conducted in West Africa, 27.4% of physicians were found to have had training[22]. This rate in our study was low, and hospitals should provide group training on this issue to improve it. This rate was substantially higher among nonsurgical physicians. Given that nonsurgical physicians have greater PV expertise, it can be concluded that they are more interested in PV.

In another study conducted in Turkey, 9.5% of physicians reported that the PCP informed them about the procedure for reporting ADRs, similar to our study[7]. Likewise, this percentage was 26.1% for nurses in a study from Turkey[16]. When the literature and the results of this study are analysed together, it can be stated that the PCP officers’ informative efforts produced better outcomes in nurses than in physicians, or that these activities were conducted more intensely for nurses.

For the PV and ADR notification applications to reach the desired level of success, healthcare practitioners’ knowledge of this topic must be current. This can be fulfilled by observing current trends. The low rate implies that awareness of these topics is inadequate.

Our study had a few limitations. Raising the number of participants could produce a more accurate reflection of the issue. Face-to-face administration of the survey would have resulted in a greater response rate. In addition, it was not possible to reach a sufficient number of physicians from each clinical specialty. In order to compare the outcomes, internal and surgical branches were separated. If a significant number of physicians from each clinical branch were to be recruited, comparisons between branches would be conceivable. Since only the physicians were included in the study, results for other healthcare professionals could not be obtained, nor could a comparison be performed with physicians and the other healthcare professionals.

Future studies can be derived from the findings of our study. Using a questionnaire administered before and after an online or face-to-face training programme, the contribution of the training to physicians’ PV knowledge and attitudes could be determined.

**CONCLUSION**

We observed that physicians’ PV expertise was insufficient. Nonsurgical physicians had a higher PV knowledge than surgeons had. The number of participants having a positive attitude towards PV was higher than the rate of their knowledge level. The majority of physicians viewed the reporting of ADRs as a professional obligation and believe that PV education should be comprehensively provided to healthcare professional. Despite this, physicians were unsure of what to do in the event of ADRs. Although 50% of physicians have encountered an ADR, the rate of seeing the ADR form and completing it were low. The number of individuals obtaining training on how to complete the ADR form was low.

**ARTICLE HIGHLIGHTS**

***Research background***

The activities and scientific studies conducted to detect, evaluate, understand, or prevent adverse reactions and other drug-related problems constitute pharmacovigilance (PV). There are studies analysing the PV knowledge of healthcare professionals in Turkey and worldwide but more extensive research is required on this topic.

***Research motivation***

Due to their shared responsibility for PV applications, each healthcare professional must investigate PV with care. The knowledge, attitudes, and actions of healthcare personnel regarding PV can have an immediate effect on patient safety.

***Research objectives***

In order to assess the knowledge, experience, and perspectives of clinicians regarding PV and reporting adverse drug reactions (ADRs), this study intended to administer a questionnaire to as many physicians from as many institutions as possible.

***Research methods***

The study was analytical and cross-sectional. Using a questionnaire, data were collected. The questionnaire was emailed out. The survey was sent to 2030 physicians and 670 of them participated.

***Research results***

PV was correctly defined by 53.9% of participants according to the most accurate definition. The most significant objective of PV was correctly identified by 54.9% of participants. The PV knowledge of nonsurgical physicians was superior to that of surgeons. ADR reporting forms were filled out by 80.9% of physicians who encountered ADRs.

***Research conclusions***

Insufficient PV knowledge was observed among physicians. The percentage of participants with a favourable attitude toward PV exceeded the percentage of those with a high level of knowledge. Although 50% of physicians had encountered ADRs, the rate of filling out the ADR reporting form was low. The proportion of individuals who received training on how to complete the ADR reporting form was also low.

***Research perspectives***

The acquired data will be used to identify the problems of physicians in the field of PV, to enhance the current situation, and to serve as a basis for future research in this area.

**REFERENCES**

1 **World Health Organization.** The safety of medicines in public health programmes: Pharmacovigilance, an essential tool. France: World Health Organization, 2006. [cited 3 May 2023]. Available from: https://apps.who.int/iris/handle/10665/43384

2 **World Health Organization.** The importance of pharmacovigilance. United Kingdom: World Health Organization, 2002. Jan 1, 2002. [cited 3 May 2023]. Available from: https://www.who.int/publications/i/item/10665-42493

3 **Campbell JE**, Gossell-Williams M, Lee MG. A Review of Pharmacovigilance. *West Indian Med J* 2014; **63**: 771-774 [PMID: 25867582 DOI: 10.7727/wimj.2013.251]

4 **Fornasier G**, Francescon S, Leone R, Baldo P. An historical overview over Pharmacovigilance. *Int J Clin Pharm* 2018; **40**: 744-747 [PMID: 29948743 DOI: 10.1007/s11096-018-0657-1]

5 ERGÜN Y. Farmakovijilans: TürkMevzuatıAçısından Bir Değerlendirme. KahramanmaraşSütçü İmam ÜniversitesiTıpFakültesiDergisi. 2019;14(3):155-61 [DOI:10.17517/ksutfd.538002]

6 Kubat H. Hekimlerinakılcıilaçkullanımıvefarmakovijilansayönelikbilgivetutumları. Cukurova Medical Journal. 2018;43(2):286-94 [DOI:10.17826/cumj.341469]

7 **Ergün Y**, Ergün TB, Toker E, Ünal E, Akben M. Knowledge attitude and practice of Turkish health professionals towards pharmacovigilance in a university hospital. *Int Health* 2019; **11**: 177-184 [PMID: 30265317 DOI: 10.1093/inthealth/ihy073]

8 **Toklu HZ,** an Soyalan M, Gültekin O, Özpolat M, AydınMD, Günay AÇ, Yavuz DÖ, AkiciA, DemirdamarR. The knowledge and attitude of the healthcare professionals towards pharmacovigilance and adverse drug reaction reporting in Northern Cyprus. *J Pharmacovigil* 2016 [DOI:10.4172/2329-6887.1000193]

9 **Alsaleh FM**, Lemay J, Al Dhafeeri RR, AlAjmi S, Abahussain EA, Bayoud T. Adverse drug reaction reporting among physicians working in private and government hospitals in Kuwait. *Saudi Pharm J* 2017; **25**: 1184-1193 [PMID: 30166908 DOI: 10.1016/j.jsps.2017.09.002]

10 **Pellegrino P**, Carnovale C, Cattaneo D, Perrone V, Antoniazzi S, Pozzi M, Napoleone E, Filograna MR, Clementi E, Radice S. Pharmacovigilance knowledge in family paediatricians. A survey study in Italy. *Health Policy* 2013; **113**: 216-220 [PMID: 24012386 DOI: 10.1016/j.healthpol.2013.08.006]

11 **Aydin OC**, Aydin S, Guney HZ. Pharmacovigilance and radiologists: How well do they get along? *Br J Radiol* 2020; **93**: 20200596 [PMID: 32903029 DOI: 10.1259/bjr.20200596]

12 **Güner MD**, Ekmekci PE. Healthcare professionals' pharmacovigilance knowledge and adverse drug reaction reporting behavior and factors determining the reporting rates. *J Drug Assess* 2019; **8**: 13-20 [PMID: 30729064 DOI: 10.1080/21556660.2019.1566137]

13 **Katusiime B**, Semakula D, Lubinga SJ. Adverse drug reaction reporting among health care workers at Mulago National Referral and Teaching hospital in Uganda. *Afr Health Sci* 2015; **15**: 1308-1317 [PMID: 26958036 DOI: 10.4314/ahs.v15i4.34]

14 **Lemay J**, Alsaleh FM, Al-Buresli L, Al-Mutairi M, Abahussain EA, Bayoud T. Reporting of Adverse Drug Reactions in Primary Care Settings in Kuwait: A Comparative Study of Physicians and Pharmacists. *Med PrincPract* 2018; **27**: 30-38 [PMID: 29402876 DOI: 10.1159/000487236]

15 **Datta S**, Sengupta S. An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting in a tertiary care teaching hospital of Sikkim. *Perspect Clin Res* 2015; **6**: 200-206 [PMID: 26623391 DOI: 10.4103/2229-3485.167096]

16 **Tiftik N,** Duman İ, İsmail Ü. Bir Üniversite Hastanesinde Görev Yapan Hemşirelerin Farmakovijilans Hakkında Bilgi, Tutumve Uygulamalarının Değerlendirmesi. *Mersin Üniversitesi Tıp Fakültesi Lokman Hekim Tıp Tarihive Folklorik Tıp Dergisi* 2019; **9**: 285-293 [DOI: 10.31020/mutftd.581540]

17 **Syed A**, Azhar S, Raza MM, Saeed H, Jamshed SQ. Assessment of Knowledge, Attitude and Barriers towards Pharmacovigilance among Physicians and Pharmacists of Abbottabad, Pakistan. *Pharmacy (Basel)* 2018; **6** [PMID: 29614725 DOI: 10.3390/pharmacy6020029]

18 **Abdel-Latif MM**, Abdel-Wahab BA. Knowledge and awareness of adverse drug reactions and pharmacovigilance practices among healthcare professionals in Al-Madinah Al-Munawwarah, Kingdom of Saudi Arabia. *Saudi Pharm J* 2015; **23**: 154-161 [PMID: 25972735 DOI: 10.1016/j.jsps.2014.07.005]

19 **Gahr M**, Eller J, Connemann BJ, Schönfeldt-Lecuona C. Subjective Reasons for Non-Reporting of Adverse Drug Reactions in a Sample of Physicians in Outpatient Care. *Pharmacopsychiatry* 2016; **49**: 57-61 [PMID: 26744100 DOI: 10.1055/s-0035-1569291]

20 **GeitonaM,** Toska A, Latsou D, Saridi M, Evripidou A, Evripidou I. Antibiotics' prescribing and pharmacovigilance attitudes among pediatricians and pediatric residents in Cyprus. *Pharmacol Pharm* 2017; **8**: 75-84 [DOI: 10.4236/pp.2017.83005]

21 **Thürmann PA**, Schmitt K. [Detection and evaluation of adverse drug effects]. *Med Klin (Munich)* 2000; **95**: 4-8 [PMID: 10851841]

22 **Sabblah GT**, Akweongo P, Darko D, Dodoo AN, Sulley AM. Adverse drug reaction reporting by doctors in a developing country: a case study from Ghana. *Ghana Med J* 2014; **48**: 189-193 [PMID: 25709133 DOI: 10.4314/gmj.v48i4.4]

**Footnotes**

**Institutional review board statement:** This cross-sectional analytical investigation was approved by the Gazi University Clinical Research Ethics Committee, No. 25901600-604.01.01-16.

**Informed consent statement:** The study included everyone who agreed to participate in the survey.

**Conflict-of-interest statement:** All the authors report no relevant conflicts of interest for this article.

**Data sharing statement:** All data will be shared with the relevant parties upon request atozlemclk\_89@hotmail.com.

**CONSORT 2010 statement:** The authors have read the CONSORT 2010 statement, and the manuscript was prepared and revised according to the CONSORT 2010 statement.

**Open-Access:** This article is an open-access article that was selected by an in-house editor and fully peer-reviewed by external reviewers. It is distributed in accordance with the Creative Commons Attribution NonCommercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: https://creativecommons.org/Licenses/by-nc/4.0/

**Provenance and peer review:** Invited article; Externally peer reviewed.

**Peer-review model:** Single blind

**Peer-review started:** February 21, 2023

**First decision:** April 10, 2023

**Article in press:**

**Specialty type:** Medicine, research and experimental

**Country/Territory of origin:** Turkey

**Peer-review report’s scientific quality classification**

Grade A (Excellent): 0

Grade B (Very good): 0

Grade C (Good): C, C

Grade D (Fair): 0

Grade E (Poor): 0

**P-Reviewer:** Havali C, Turkey; Li WJ, United States **S-Editor:** Li L **L-Editor:** Kerr C **P-Editor:**

**Table 1 Age distribution of the participants**

|  |  |
| --- | --- |
| **Age range , yr** | ***n* (%)** |
| 18-25 | 19 (3) |
| 26-35 | 388 (61.9) |
| 36-44 | 103 (16.4) |
| 45 and more | 117 (18.7) |
| Total | 627 (100) |

**Table 2 Specialty distribution of the participants**

|  |  |
| --- | --- |
| **Specialization** | ***n* (%)** |
| Emergency medicine | 40 (6.4) |
| Family medicine | 79 (12.6) |
| Anaesthesiology and resuscitation | 49 (7.8) |
| Brain surgery | 13 (2.1) |
| Paediatric surgery | 3 (0.5) |
| Child psychiatry | 7 (1.1) |
| Dermatology | 6 (1) |
| Infectious diseases and clinical microbiology | 11 (1.8) |
| Physical medicine and rehabilitation | 29 (4.6) |
| General surgery | 9 (1.4) |
| Thoracic surgery | 20 (3.2) |
| Chest diseases | 19 (3.2) |
| Eye diseases | 15 (2.4) |
| Public health | 5 (0.8) |
| Internal diseases | 85 (13.6) |
| Gynaecology and obstetrics | 22 (3.5) |
| Cardiology | 16 (2.6) |
| Ear nose throat and diseases | 5 (0.8) |
| Cardiovascular surgery | 4 (0.6) |
| Neurology | 19 (3) |
| Orthopaedics and traumatology | 17 (2.7) |
| Pathology | 5 (0.8) |
| Paediatrics | 48 (7.7) |
| Psychiatry | 43 (6.9) |
| Radiology | 24 (3.8) |
| Medical genetics | 18 (2.9) |
| Urology | 16 (2.6) |
| Total | 627 (100) |

**Table 3 Professional experience levels distribution of participants**

|  |  |
| --- | --- |
| **Yr of experience** | ***n* (%)** |
| ≤ 4 | 164 (26.2) |
| 5–9  | 245 (39.1) |
| 10–14  | 67 (10.7) |
| ≥ 15  | 151 (24.1) |
| Total | 627 (100) |

**Table 4 Ranking of participants’ reasons for not reporting adverse drug reactions**

|  |  |
| --- | --- |
| **Reason** | **% (Ratio)** |
| Difficulty in deciding whether ADRs have occurred | 54 (320/592) |
| Insufficient time to report ADR | 52 (312/592) |
| Consideration that the ADR is not significant enough to be reported | 46 (275/592) |
| The absence of any reward for reporting | 45 (270/592) |
| Believing that licensed drugs are safe | 43 (255/592) |
| The notion that a single unreported ADR will not affect the database | 41 (247/592) |
| Not knowing how to make a notification | 34 (203/592) |

ADR: Adverse drug reactions.