

# Pharmacist's Knowledge and Behaviors Toward Pharmacovigilance and Adverse Drug Reactions Reporting Process in Turkey

**Short title: Pharmacist's Knowledge and Behaviors toward Pharmacovigilance**

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## Abstract

**INTRODUCTION:** Adverse drug reactions (ADRs) increase patient-related morbidity and mortality. In addition, it is an important public health problem associated with prolonged hospital stay and increasing economic burden. Pharmacovigilance plays an important role in reducing ADRs, so the development and growth of this science is critical to effective and safe clinical practice. The aim of the study is to evaluate the knowledge and behavior of pharmacists towards pharmacovigilance and spontaneous ADR notifications in Turkey.

**METHODS:** The online questionnaire method was used with the pharmacists whose prior consent was obtained to participate in the study. The survey was uploaded onto Google Form. The survey link was distributed electronically to the eligible participants via social media channels. The knowledge of pharmacovigilance practice, ADR reporting compliance rates, reasons for not reporting ADR and perceptions of the Turkish pharmacists on pharmacovigilance practice were evaluated.

**RESULTS:** 406 pharmacists (45%) agreed to participate in the study. 81.8% of the pharmacists correctly defined the term pharmacovigilance. 91.6% knew the name of Turkish Pharmacovigilance Center. Clinical pharmacists and hospital pharmacists were found to be more adequate knowledge than community pharmacists ( $p < 0.05$ ). 18.7% of pharmacists stated that they had previously reported ADRs. Most of the pharmacists stated that the most important reason for not reporting ADRs was not knowing how and where spontaneous reporting should be done, a single spontaneous reporting would not make a difference and the report would generate extra work.

**CONCLUSION:** These results showed that Turkish pharmacists had sufficient knowledge about the concept of pharmacovigilance and the spontaneous ADR reporting system. However, they had little experience in reporting. Training programs should continue to increase the knowledge and reporting experience of pharmacists about the reporting process and requirements.

**Keywords:** Adverse Drug Reaction Reporting System, pharmacists, pharmacovigilance, knowledge, behavior

## INTRODUCTION

Adverse drug reactions (ADRs) increase patient-related morbidity and mortality. In addition, it is an important public health problem associated with prolonged hospital stay and increasing economic burden [1,2]. Pharmacovigilance plays an important role in reducing ADRs, so the development and growth of this science is critical to effective and safe clinical practice. The World Health Organization (WHO) defines pharmacovigilance as "science and activities related to the detection, evaluation, understanding, and prevention of side effects or other possible drug-related problems" [3].

Healthcare professionals play an important role in providing a robust pharmacovigilance system. Consumers are more likely to report ADRs to their physicians or pharmacists than to the pharmaceutical industry [4]. All health system sectors should be included in the reporting process [5]. Pharmaceutical care involves assessing these risks on a patient-by-patient basis by "identifying and solving (or preventing)" drug therapy problems. Therefore, pharmacists have an important role in safe drug use and should be aware of this [6]. Unfortunately, the rate of self-reporting of ADRs by healthcare professionals around the world is extremely low, as it is not a mandatory requirement in most countries [4]. After the thalidomide disaster in the 1960s, many countries developed their national pharmacovigilance centers [7]. "Turkey Adverse Drug Effects Monitoring and Evaluation Center" (TADMER) is Turkey's first national pharmacovigilance center and was established in 1985. In 2005, its name was changed to "Turkish Pharmacovigilance Center" (TUFAM). According to the regulations, all healthcare professionals are obliged to report a serious and unexpected ADR to TUFAM within 15 days, either directly by post, fax, or e-mail, or through the pharmacovigilance contact point in the healthcare institutions where they work [8]. Many studies of other countries show the role and attitudes of pharmacists in ADR reporting [9-13]. There is a limited number of studies evaluating the knowledge and behavior of pharmacists regarding pharmacovigilance and spontaneous ADR reporting in Turkey [14]. The study aims to evaluate the knowledge and behaviors of pharmacists regarding pharmacovigilance system and spontaneous ADR reporting in Turkey.

## MATERIALS AND METHODS

### *Study design and settings*

This cross-sectional study was conducted between April 10 and May 10, 2021. The online questionnaire method was used with the pharmacists whose prior consent was obtained to participate in the study. The survey was uploaded onto Google Form. The first page of the survey contained information about the research subject. There was an option to either consent to or refuse participation in the survey at the end of this page. Individuals who chose to participate were allowed to complete the survey. The survey link was distributed electronically to the eligible participants via social media channels (Instagram, WhatsApp, and Facebook). Ethical approval for this study was obtained from the Gazi University Ethics Committee (approved number and date 2021-445 / 06.04.2021).

### *Sampling technique and sample size*

An online questionnaire was applied to randomly selected community pharmacists, hospital pharmacists, and clinical pharmacists in Turkey. Academic pharmacists working at the university and non-active pharmacists were not included in the study.

Considering a total of 32.000 pharmacists in Turkey, the online Raosoft sample size calculator estimated the sample size of a minimum of 380 pharmacists to provide a 95% confidence level with a 5% margin of error, assuming 50% of pharmacists express good knowledge.

### ***Data collection***

The questionnaire items and question selection were based on previous research and interviews with senior pharmacists on this subject. A draft questionnaire was created to be subjected to tests and examinations by community pharmacists (n = 10) and hospital pharmacists (n = 10). The survey questions were then adjusted according to the qualitative feedback provided by the respondents and the results of the internal validity measurement. Cronbach alpha score was 0.6. There are 19 questions in the study. The first 5 questions are based on the demographic information of the participants, 6-11 questions are about knowledge, 12-18 are questions about behaviors.

### ***Statistical analysis***

Statistical analyses of the main survey data were performed using IBM SPSS (version 24.0) with significance levels set at  $p \leq 0.05$ . Demographic variables and responses given to knowledge and behavior questions were analyzed using descriptive statistics. Descriptive analyses were used to present the results as percentages and frequencies. For knowledge questions, correct answers were scored as 1, and wrong answers are scored as 0. 6 questions were calculated as 6 points and correspond to 100%. A score of more than 80% was accepted as adequate knowledge, while a total score  $\leq 80\%$  was classified as inadequate knowledge. Scoring was not done for behavior questions. Association between patients' socio-demographic characteristics and ADR knowledge was also done using the Pearson Chi-square test.

### **RESULTS**

The questionnaires were sent to 900 pharmacists in total, but 406 pharmacists (45%) agreed to participate. 73.4% of the respondents were women and 51.3% of the respondents were between the ages of 22-29. 65% of the respondents were community pharmacists, 21.4% were hospital pharmacists and 13.5% were clinical pharmacists. 54.2% of the respondents had a working period as a pharmacist less than 5 years and 17.2% of them have a postgraduate degree. Socio-demographic characteristics of pharmacists are summarized in Table 1.

#### ***Knowledge***

Table 2 demonstrates the responses to questions related to knowledge. 81.8% of the respondents defined the term pharmacovigilance correctly. 46.3% of the respondents answered correctly the location of the world pharmacovigilance center. 91.6% knew the name of Turkey's national pharmacovigilance center. 79.8% of the respondents answered correctly who could report ADRs and 83.3% knew which ADRs could be reported correctly. 70.4% of the respondents knew how to report an ADR. Table 3 shows the association with socio-demographic characteristics of patients and pharmacovigilance awareness, as well as ADR knowledge and reporting of previously experienced ADRs. 57.6% of the respondents had sufficient knowledge of ADRs. The relationship of ADRs information with age, gender, duration of the study, and postgraduate degree was not found to be statistically significant ( $p > 0.05$ ). The relationship between the pharmacist's work area (clinical pharmacist or hospital pharmacist or pharmacy pharmacist) and the previous reporting of ADRs was significant ( $p < 0.05$ ). Clinical pharmacists and hospital pharmacists were found to be better knowledge levels than community pharmacists.

#### ***Behaviors***

Table 4 shows that pharmacists' behaviors towards reporting ADRs. 40.4% of pharmacists stated that they did not experience ADRs in their patients at all, 39.9% experienced them once a year, 15.8% once a month, and 3.9% once a week. Previously, 76 pharmacists (18.7%) were found in the ADRs notification.

55.2% were serious, 31.5% were unexpected and 5% were rare type ADRs. 99.5% of the respondents stated that it was important to report ADRs. The relationship between the pharmacist's work area (clinical pharmacist, hospital pharmacist or community pharmacist) and the previous reporting of ADRs was significant ( $p < 0.05$ ). 35.6% of hospital pharmacists, 23.6% of clinical pharmacists and 12.1% of community pharmacists who participated in our study declared that they had previously reported ADRs.

Most of the respondents (36.9%) stated that the most important reason for not reporting ADRs was that they did not know how and where spontaneous reporting should be done. 19.2% of them stated that a single spontaneous reporting would not make a difference and 18.7% stated that the report would generate extra work (Table 5). Among the factors that encourage reporting ADRs are; the reaction was serious (31.5%), the reaction was unexpected (22.7%), the training of health care professionals (19.2%), and the reporting process was practical and easy (17.7%). (Table 6).

## **DISCUSSION**

The results of our study revealed that although Turkish pharmacists had sufficient pharmacovigilance and theoretical knowledge about ADRs, they showed a low rate of ADR reporting. 81.8% of the respondents correctly defined the term pharmacovigilance. This was a fairly high rate. In the study conducted by Kopciuch et al. [10] 73% of the respondents, 69.5% of the respondents in the study conducted by Changai Su et al. [15], and 81.9% of the respondents in the study conducted by Li et al. [11] defined the term pharmacovigilance correctly. In the study conducted by Suyagh et al. [16] 25.5% of the participants correctly defined the term pharmacovigilance. In Turkey, 91.6% of the respondents knew the national ADRs reporting location correctly. While nearly half of the respondents in the study conducted by Kopciuch et al. [10] knew correctly, in the study conducted by Suyagh et al. [16] 76% of the respondents declared that they did not know where to find the necessary forms for ADR reporting and 60% of the respondents did not know the national pharmacovigilance center in the study conducted by Vigneshwaran et al. [17]. Toklu et al. [14] evaluated the knowledge and attitudes of pharmacy pharmacists in Turkey regarding ADRs in 2008. In the study, 17% of pharmacists correctly defined pharmacovigilance. This low rate may have resulted from the question being an open-ended question and it was only 3 years ago that the regulation on the pharmacovigilance system (Regulation on Monitoring and Evaluation of the Safety of Medicinal Products for Human Use) came into force. 87% of pharmacists did not know where to get ADRs reporting forms. The results of our study showed that the level of knowledge on pharmacovigilance and ADRs reporting increased significantly in Turkey. This was because pharmacovigilance courses are given more place in the bachelor's degree. In our study, 40.4% of pharmacists stated that they had never seen ADRs in their patients. This was a high rate. In the study conducted by Suyagh et al. [16], 8% of the patients never reported to their pharmacist when ADRs developed. This might be because patients in Turkey did not consult pharmacists when ADRs had developed. In the patient information leaflet of some medicines in Turkey, there is the phrase "consult your doctor when you have an unexpected side effect". This statement may have prevented patients who experienced ADRs the pharmacist from consulting when ADRs develop. Pharmacists should also be added to this statement in the patient information leaflet. Although 99.5% of the pharmacists thought that ADRs reporting was important, 18.7% of pharmacists previously reported ADRs. This ratio was also supported by other scientific reports that concluded that the rates of ADRs reported by pharmacists in various countries ranged from 14.6% to 38% [10, 11, 15, 17-19]. But this ratio was 7% in the study conducted by Toklu et al. [14] This situation shows that the ADRs reporting rate has increased in Turkey.

## **CONCLUSION**

These results showed that Turkish pharmacists had sufficient knowledge about the concept of pharmacovigilance and the spontaneous ADR reporting system. However, they had little experience in ADRs reporting. Training programs should be ongoing to enhance the role of pharmacists and their knowledge of the reporting process and requirements and the reporting experience.

*Conflict of interest: No conflict of interest was declared by the authors. The authors are solely responsible for the content and writing of this paper.*

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**Table 1. Demographic characteristics of pharmacists (n = 406)**

Variables	n (%)
<b>Gender</b>	
Female	298 (73.4)
Male	108 (26.6)
<b>Age, ranges</b>	
22-29	210 (51.7)
30-44	82 (20.2)
45-59	90 (22.2)
>60	24 (5.9)
<b>Work place</b>	
Community pharmacist	264 (65)
Hospital pharmacist	87 (21.4)
Clinical pharmacist	55 (13.5)
<b>Experience as a pharmacist</b>	
<5 years	220 (54.2)
≥5 years	186 (45.8)
<b>Postgraduate degree (MSc, PhD)</b>	
Yes	70 (17.2)
No	336 (82.8)

**Table 2. Knowledge of the pharmacists concerning pharmacovigilance and reporting ADR**

Questions	n (%)
<b>What is pharmacovigilance?</b>	
Adverse drug reaction reporting	52 (12.8)

Detection, recognition, evaluation and prevention of adverse drug reactions*	332 (81.8)
The science of evaluating the benefit / risk profile of a medicinal product	16 (3.9)
Don't know	6 (1.5)
<b>Where is the World Pharmacovigilance Center located?</b>	
United States of America	174 (42.9)
France	30 (7.4)
United Kingdom	14 (3.4)
Sweeden*	188 (46.3)
<b>Which institution is responsible for adverse reaction reporting and monitoring in Turkey?</b>	
TUFAM*	372 (91.6)
The Regional Board of pharmacists	-
Turkish Pharmacists Association	20 (4.9)
Don't know	14 (3.4)
<b>Who can spontaneously report adverse drug reactions?</b>	
Doctor	12 (3)
Pharmacist	70 (17.2)
Dentist	-
Nurse	-
All of above*	324 (79.8)
<b>What types of adverse drug reactions are expected to be reported?</b>	
Serious and unexpected	58 (14.3)
Not serious	-
Expected adverse reactions	2 (0.5)
All adverse reactions regardless of seriousness and expectedness*	338 (83.3)
Don't know	8 (2)
<b>Do you know how to report adverse drug reactions?</b>	
Yes*	286 (70.4)
No	120 (29.6)

\* :True answer

**Table 3. Association between pharmacists demographic characteristics and pharmacovigilance awareness, adverse drug reaction knowledge towards adverse drug reaction reporting**

Variables	ADR Knowledge	
	Adequate (Score > 80%)	Inadequate (Score <80%)
<b>Gender</b>	p>0.05	
<b>Female</b>	176 (75.2)	122 (70.9)
<b>Male</b>	58 (24.8)	50 (29.1)
<b>Age (years)</b>	p>0.05	
22-29	132 (56.4)	78 (45.3)
30-44	52 (22.2)	30 (17.4)
45-59	38 (16.2)	52 (30.2)
>60	12 (5.1)	12 (7)
<b>Work place</b>	p=0.01	
Community pharmacist	128 (54.7)	136 (79.1)
Hospital pharmacist	63 (26.9)	24 (14)
Clinical pharmacist	43 (18.4)	12 (7)
<b>Experience as a pharmacist</b>	p>0.05	

	n (%)	
<b>How often do you see ADRs in patient?</b>		
Once a week	16 (3.9)	
Once a month	64 (15.8)	
Once a year	162 (39.9)	
Never	164 (40.4)	
<b>Have you ever previously reported adverse drug reactions?</b>		
Yes	76 (18.7)	
No	330 (81.3)	
<b>If you have reported, what type of adverse drug reaction was the most common?<sup>a</sup></b>		
Serious	42 (55.2)	
Rare	10 (13.1)	
Unexpected	24 (31.5)	
<b>Do you think adverse reaction reporting is important and necessary?</b>		
Yes	404 (99.5)	
No	2 (0.5)	
<b>If your answer is yes, what is the most important reason?<sup>b</sup></b>		
To increase patient safety	-	
To indicate relatively safe drugs	190 (47)	
To determine the incidence of adverse reactions	74 (18.3)	
To identify new adverse reactions	140 (34.6)	
<5 years	136 (58.1)	84 (48.8)
≥5 years	98 (41.9)	88 (51.2)
<b>Postgraduate degree (MSc, PhD)</b>	p>0.05	
Yes	44 (18.8)	26 (15.1)
No	190 (81.2)	146 (84.9)

**Table 4. Pharmacists behaviors towards reporting ADRs**

<sup>a</sup> n=76, <sup>b</sup> n=404

**Table 5. The most important factor that may discourage pharmacists from reporting adverse drug reactions**

	n (%)
Lack of time to complete reports	48 (11.8)
Concern that the report will generate extra work	76 (18.7)
Not paying a fee for notification	2 (0.5)
Concern about submitting an inappropriate report	18 (4.4)

Not knowing how and where spontaneous reporting should be done	150 (36.9)
Incomplete medical history of the patient	34 (8.4)
The idea that a single spontaneous reporting cannot make a difference	78 (19.2)

**Table 6. The most important factor that encourages pharmacists to report adverse drug reactions**

	<b>n (%)</b>
Reaction to a new drug	16 (3.9)
Unexpected reaction	92(22.7)
Serious reaction	128 (31.5)
Payment asset for instant reporting	8 (2)
Requiring spontaneous notification	12 (3)
Practical and easy spontaneous reporting process	72 (17.7)
Training of healthcare professionals	78 (19.2)

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