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The perspective of pharmacist on pharmacovigilance and adverse drug reaction reporting in Asir region, Saudi Arabia

Y. ALGHAZWANI[1], A.M. ALQAHTANI[1], M.K. ALSHURAYMI[2], I.M. ASSIRI[2], A.A. SHUFLUT[2], V. KRISHNARAJU[1], C. KUMARAPPAN[1], A.R.N. IBRAHIM[3,4], K. ORAYJ[3]

[1]Department of Pharmacology, [2]College of Pharmacy, King Khalid University, Al-Qara, Asir Province, Saudi Arabia
[3]Department of Clinical Pharmacy, College of Pharmacy, King Khalid University, Al-Qara, Asir Province, Saudi Arabia
[4]Department of Biochemistry, Faculty of Pharmacy, Minia University, Minia, Egypt

Abstract. – OBJECTIVE: Adverse drug reactions (ADRs) are widespread worldwide, and their intervention is critical to patient safety and healthcare quality. Pharmacists are essential in monitoring and reporting ADRs, directly influencing patient care. This study aimed to examine the prevalence of ADRs among pharmacists and their knowledge regarding ADRs, including the factors affecting ADR reporting.

SUBJECTS AND METHODS: From September 2021 to November 2021, a cross-sectional survey among pharmacists in the Asir area of Saudi Arabia was planned. This study involved contacting 97 pharmacists using a cluster sampling method. The study's goals were met using a 25-item self-administered questionnaire. Data analysis was done using SPSS version 25 (IBM Corp., Armonk, NY, USA).

RESULTS: Ninety-seven pharmacists (male 53.6% and female 46.4%) completed the survey. More than three-fourths of the participants (78.4%) know the ADR reporting system. The survey was completed by 97 pharmacists (male 53.6% and female 46.4%). More than three-quarters of the participants (78.4%) were aware of the ADR reporting system, and the majority (70.8%) were aware that it is done using an online system. Still, only 56.7% knew that the Saudi FDA is the regulatory agency collecting ADR data in Saudi Arabia. Furthermore, 73.2% cited stress in the workplace as a critical deterrent to reporting. Most respondents (76.3%) had an unfavorable attitude about reporting ADRs.

CONCLUSIONS: Pharmacists understand ADR reporting, but most lack the mentality to report the incidents. As a result, comprehensive and ongoing training for pharmacists is required to raise awareness on the need for ADR reporting.

Key Words:
Pharmacist, Adverse drug reactions, Attitudes, Knowledge, Perception, Pharmacovigilance.

Introduction

While drugs are utilized worldwide to achieve therapeutic goals, they can also have unfavorable side effects[1]. A medicine's approval is based on well-controlled and regulated clinical studies. Preclinical and clinical studies do not disclose all significant and latent adverse drug reactions (ADRs) of investigational treatments, necessitating post-marketing surveillance of all products. The efficacy and safety of these medicines are assessed throughout time. Healthcare workers report most adverse drug reactions after taking prescription medications[2]. ADR reporting is recognized as a significant source of information for healthcare providers, and the quality of ADR reports obtained is dependent mainly on the data presented. Pharmacists play a critical role in ensuring the continued safety of medications[3]. It is especially true when pharmacists' professional practices increasingly include drug treatment management through pharmaceutical care. The pharmacist practitioner's ability to offer a patient's entire medication history substantially benefits medicine surveillance[4-6].

Pharmacists' roles in ADR reporting have evolved over the past decade. However, they differ by region[7-9]. Pharmacists in Scandinavian nations were not permitted to report ADRs independently until around a decade ago[10]. In the United Kingdom, pharmacists were only allowed to report ADRs independently after a ten-year discussion and debate[11]. On the other hand, in Malaysia, pharmacists were responsible for more than half of the total ADRs reports re-

Corresponding Author: Yahia Alghazwani, Ph.D; e-mail: ysghazwani@kku.edu.sa

ceived by the Malaysian National Pharmacovigilance Center in 2010[12]. In 2004, a worldwide assessment of 41 member nations participating in the WHO Drug Monitoring program discovered significant differences in pharmacists' roles in reporting ADRs[13]. The transformation of pharmacists' roles within healthcare systems worldwide from "dispensers" to "guardians of medication safety and patient outcomes" may help explain this trend.

The Saudi Food and Drug Authority (SFDA) has established a National Pharmacovigilance Center, making online and paper reporting forms available to promote general and healthcare professionals' ADR reporting[14]. Willful reporting of ADRs is an essential component of medical drug safety. It is often difficult for healthcare providers to address ADR-related occurrences due to a significant lack of information about ADR reporting. A recent study[15] identified some key factors that can effectively address pharmacists' under-reporting of ADRs and improve medication safety. Another research[16] in Saudi Arabia found that ADR-specific education was linked to a considerable improvement in pharmacists' knowledge and awareness of ADRs and reporting techniques. SFDA must provide local reports because it is a WHO Uppsala Monitoring Centre member[17]. As a result, pharmacist knowledge and attitudes about ADR reporting are critical indicators of the healthcare services delivered to patients. This study aimed to investigate pharmacist knowledge, attitudes, and behaviors on ADR reporting in Saudi Arabia's Asir area.

Subjects and Methods

Study Design and Participants

Between September 2021 and November 2021, a cross-sectional online survey was administered. Before conducting this survey, we validated the questionnaire on a subset of participants to ensure the questions were clear and understandable. Additionally, we conducted the Cronbach alpha test to examine the internal consistency (the content of the study tool). They were polled using a questionnaire that asked about their demographics, understanding, attitude, and conduct of ADRs reporting.

In the Asir region, the questionnaire was sent to many pharmacists to reach a sample size of around 100.

Contents of the Study Tool

Participants' opinions on ADRs and impediments to reporting were recorded using a 25-item self-administered questionnaire. Five parts were made up of the questionnaire. The first section consisted of eight items, most concentrating on demographics and pharmacy-related information. The second section aimed to assess pharmacists understanding of ADR reporting, and four items were used. The third section had two questions about pharmacist behavior regarding ADR reporting. The fourth section comprised five questions about the frequency of ADR exposure. The final portion of the survey was designed to document the pharmacist's role in patient counselling regarding ADRs. The Cronbach alphas were used to analyze the questioners' internal consistency, and the result was 0.65, which is acceptable.

Data Collection and Ethical Consideration

After discussing the study's goals, Pharm.D final year pharmacy students visited several healthcare facilities and handed questionnaires to various participants. Each participant signed a written consent form to take part in the study. Participants were advised that all information they gave would be kept private and that the findings would be presented anonymously. Questions that may reveal the pharmacists' or pharmacy's identities (i.e., contact numbers, names, drugstore names) were avoided. The Deanship of Scientific Research of King Khalid University provided institutional approval.

Statistical Analysis

The questionnaires were checked for completeness and accuracy, and the data was cleaned, coded, and entered into SPSS version 25 (IBM Corp., Armonk, NY, USA). Descriptive analysis was used to represent the sociodemographic data. Continuous variables were described as means and standard deviations, while categorical variables were reported as frequencies and percentages. Multiple logistic regression was conducted to investigate the ADRs writing factors. The dependent facets included questions that followed the Likert scale model with the answers (never, rarely, sometimes, or frequently); those questions were grouped and converted to a dichotomous dependent variable with only two options, i.e., positive behaviors *vs.* reluctant or negative be-

havior. The positive behaviors encompassed the "frequently" answer, while the hesitant or negative behaviors encompassed the rest. A specific independent variable was included in the final multiple logistic regression if bivariate logistic regression with the dependent factors yielded a *p*-value of 0.20 or less. The odds ratios and 95% confidence intervals were calculated and analyzed.

Results

Demographics and Practice Characteristics

A total of 97 pharmacists received the survey (Table I). The participants' average age was 25±4.9 years. Pharmacists with B.Sc in Pharmacy (n=44, 45.4%), Pharm.D (n=32, 33%), Masters (n=9, 9.3%), and Ph.D (n=4, 4.1%) degrees were among those who responded. Male pharmacists (n=52, 53.6%) were somewhat more numerous than female pharmacists (n=45, 46.4%). The majority (n=32, 33%) had 1-3 years of experience, followed by those with more than nine years of experience (n=24, 24.7%). More than half of them (n=57, 58.8%) were hospital pharmacists, followed by community pharmacists (n=38, 39.2%).

Table I. Demographic information of pharmacists.

Demographic	n (%) n = 97
Sex (male)	52 (53.6)
Sex (female)	45 (46.4)
Age group (years)	
20-30	49 (50.5)
30-40	31 (32)
40-50	11 (11.3)
More than 50	6 (6.2)
Educational level	
B.Sc. in pharmacy	44 (45.4)
Diploma	8 (8.2)
Masters	9 (9.3)
Pharm.D	32 (33)
Ph.D	4 (4.1)
University	
King Khalid University, Saudi Arabia	45 (46.4)
King Abdulaziz University, Saudi Arabia	6 (6.2)
Taibah University, Saudi Arabia	4 (4.1)
King Saud University, Saudi Arabia	4 (4.1)
Jazan University, Saudi Arabia	4 (4.1)
Other	34 (35.1)
Years of experience (as a pharmacist)	
< 1	17 (17.5)
1-3	32 (33)
4-6	14 (14.4)
7-9	10 (10.3)
More than 9	24 (24.7)
Type of Pharmacy (if working in a pharmacy)	
Community pharmacy	38 (39.2)
Hospital pharmacy	57 (58.8)
Primary medical center	1 (1)
Outpatient pharmacy	1 (1)

Adverse Drug Reaction (ADR) Reporting Experiences

More than half of pharmacists (56.7%) said they knew the SFDA as the regulatory agency collecting ADRs data (Table II). Three-quarters of the participants (n=71, 73.2%) said they could not disclose adverse occurrences because of work-related stress. Gastro-intestinal tract (GIT) drugs (n=44, 45.4%), cardiovascular (CVS) medications (n=20, 20.6%), and central nervous system (CNS) medications (n=10, 10.3%) were the most often reported medications to induce ADRs. CVS medicines (n=20, 20.6%), GIT medicines (n=16, 16.5%), CNS medications (n=11, 11.3%), and analgesics (n=10, 10.3%) were among the drugs or drug groups linked to significant ADRs. In addition, most pharmacists reported no substantial adverse drug reactions in the previous month (55.8%).

Pharmacist Behavior Towards ADR Reporting

One-fourth of patients (n=23, 23.7%) regularly reported ADRs, and the same percentage (n=23, 23.7%) addressed the ADR with their prescriber, but most pharmacists (n=40, 41.2%) did not report ADRs regularly (Table III, IV, V). On the other hand, over a third of the participants (35.1%) never or seldom reported ADR and never or rarely addressed ADR with prescribers (30%). Almost half of the participants (n=46, 47.4%) provide frequent counselling to their patients regarding adverse drug reactions that may be linked to their prescriptions. In addition to frequently asking female patients (n=69, 71.1%) if they are pregnant or breastfeeding, half of the volunteers (n=50, 51.5%) often inquire about patients' allergies to the medicines they are dispensing. Only 26.8% of patients were usually satisfied when receiving counselling, while the other two-thirds (67%) were seldom or occasionally satisfied (Figure 1).

Factors Affecting ADR Reporting

The logistic regression model results are given in Tables IV and V. There were no significant associations with the pertained questions in the

Table II. Pharmacists' experiences on adverse drug reaction (ADR) reporting.

Do you have internet service in the pharmacy? (Yes)	84 (86.6)
Are you familiar with the ADRs reporting system in Saudi Arabia? (Yes)	76 (78.4)
In general, can hospitals and community pharmacists report ADR? (Yes)	89 (91.8)
If YES, how can you report ADR? (n = 89)	
I don't know	6 (6.7)
Online submission	63 (70.8)
Paper submission	20 (22.5)
What is the regulatory body responsible for collecting ADR data in your sitting?	
I don't know	14 (14.4)
Saudi FDA	55 (56.7)
Ministry of Health	18 (18.6)
Pharmacy Therapeutic Committee (PTC)	5 (5.2)
Pharmacist	5 (5.2)
vHave you taken any continuing medical education (CME) about ADRs? (Yes)	55 (56.7)
What is the main difficulty in reporting ADRs?	
No clear guidelines from my institute	25 (25.8)
Stress in the work environment	71 (73.2)
Others	1 (1)
How many prescriptions, on average, do you dispense in one month?	
1-10	14 (14.4)
11-20	20 (20.6)
More than 20	55 (56.7)
Non-applicable	8 (8.2)
What are the most common ADRs encountered in your pharmacy?	
GIT medications	44 (45.4)
CVS medications	20 (20.6)
CNS medications	10 (10.3)
Respiratory system medications	9 (9.3)
Immunological medications	7 (7.2)
Others	7 (7.2)
How many ADRs have you encountered in the last month?	
None	34 (35.1)
0-5	42 (43.3)
5-10	14 (14.4)
More than 10	7 (7.2)
How many severe ADRs in last month?	
0	53 (55.8)
1	17 (17.9)
2	12 (12.6)
3	8 (8.4)
4	4 (4.2)
5	1 (1.1)
What do you think most drugs or drug classes are associated with severe ADRs?	
CVS medications	20 (20.6)
GIT medications	16 (16.5)
CNS medication	11 (11.3)
Analgesics	10 (10.3)
Respiratory medication	9 (9.3)
Antibiotics	6 (6.2)
Diabetics medications	4 (4.1)
Immunological medications	2 (2.1)
I don't know or unknown answer	19 (19.6)

univariate and multivariate logistic regression for most independent variables. However, there are some exceptions. Pharmacists who worked in hospital pharmacies have a slightly enhanced tendency toward reporting ADR compared to community pharmacists, but this was insignificant (OR: 3.201, *p*-value=0.063). Further, pharmacists who took Continuing Medical Education (CME) hours were more likely to discuss ADR compared to those who did not take CME hours (OR: 4.757, *p*-value=0.021). Furthermore, male pharmacists were more likely to ask patients if they were allergic to medications (OR: 2.968, *p*-value=0.041) and more likely to ask

Table III. Pharmacists' behavior towards ADR reporting.

Serial number	Questions	N (%) Never	N (%) Rarely	N (%) Sometimes	N (%) Frequently
1.	How often do you report ADRs that you encounter?	18 (18.6)	16 (16.5)	40 (41.2)	23 (23.7)
2.	How often do you discuss ADR with the prescriber if you encounter any?	10 (10.3)	19 (19.6)	45 (46.4)	23 (23.7)
3.	How often do you counsel your patients about ADRs associated with their medications?	4 (4.1)	8 (8.2)	39 (40.2)	46 (47.4)
4.	How often do you ask your patients if they are allergic to medications?	1 (1)	20 (20.6)	26 (26.8)	50 (51.5)
5.	When dispensing medications, how often do you ask a female patient if she is pregnant/lactating?	0 (0)	2 (2.1)	26 (26.8)	69 (71.1)
6.	How satisfied is the patient when you counsel them about ADRs?	6 (6.2)	35 (36.1)	30 (30.9)	26 (26.8)

female patients if they were pregnant (OR: 3.217, *p*-value=0.023) than females. But more samples may be needed to produce more accurate logistic regression model results.

Discussion

Pharmacovigilance (PV) is more acknowledged as critical to patient safety and the quality of Saudi Arabia's healthcare system[18]. It is our first assessment of pharmacists' views towards ADRs and self-reported behavior in the Asir region of Saudi Arabia. The study is accomplished by a questionnaire survey that assesses healthcare workers' knowledge and awareness about the pharmacovigilance systems and ADR reporting. Our findings demonstrated that three-quarters of pharmacists (n=71, 73.2%) could not report adverse occurrences owing to work-related stress. The results from this study reflect the pharmacist's lack of expertise and a negative attitude toward reporting adverse events.

Furthermore, just 56.7% are aware that the SFDA is the regulatory agency collecting ADR data, emphasizing the need for more awareness about the pharmacovigilance system among pharmacists. Our findings on pharmacist reporting of ADRs (23.7%) are better than a prior study's[19] finding which reported that only around 10% of community pharmacists have ever reported ADRs. Similarly, another study[20] found a lower reporting rate (13.5%) among Saudi community pharmacists, owing to a lack of understanding about ADR reporting.

Another intriguing result of this study is that drugs often produce ADRs. Accordingly, GIT drugs were the most prevalent source of ADRs (45.4%), followed by CVS medications (20.6%) and CNS medications (10.3%). Furthermore, the drugs often known to produce ADRs did not cause major ADRs in our investigation. This occurrence is unrelated to drugs that are known to produce major ADRs. CVS drugs cause the most significant ADRs (20.6%), followed by GIT meds (16.5%), CNS medications (11.3%), and analgesics (10.3%). The data from the Saudi Central National Pharmacovigilance and Drug Safety Center (NPC), Saudi Food and Drug Administration (SFDA), from 2015 to the end of 2017 about medications commonly reported[21] with ADRs, is in contrast with the data reported in this survey.

From 2015 to 2017, a total of 17,730 ADR instances were recorded, according to NPC-SFDA statistics[22]. A total of 54% of the ADRs reported were considered severe. Anti-infective drugs for systemic use (22.27%) were the most common medications reported with ADRs, followed by antineoplastic and immunomodulating agents (21.49%). Medications for the alimentary tract and metabolism reported 15.48% ADRs, in contrast to 45.4% in our survey. This conflict in data could be due to the smaller sample size used in our study or the reflection of dominant perception among pharmacists in this region. The most prevalent medicines linked to significant ADRs were vancomycin (2.7%), followed by ceftriaxone (1.8%), and paracetamol (1.4%). The NPC-SFDA results matched an ADR report[23] from India. According to information provided by an ADR monitoring center in India, the PV

Table IV. Univariate logistic regression model examining factors affecting the knowledge, awareness, and practice of pharmacists towards reporting ADRs.

Dependent factors Independent factors	Are you familiar with the ADRs reporting system in Saudi Arabia? (Ref = No)	How often do you report ADRs that you encounter? (Ref = negative or reluctant attitude)	How often do you discuss ADR with the prescriber if you encounteranу? (Ref = negative or reluctant attitude)	How often do you counsel your patients about ADRs associated with their medications? (Ref = negative or reluctant attitude)	How often do you ask your patients if they are allergic to medications? (Ref = negative or reluctant attitude)	When dispensing medications, how often do you ask a female patient if she is pregnant/ lactating? (Ref = negative or reluctant attitude)
	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value
Sex (Ref = female)	0.833 (0.314-2.208) 0.714	0.738 (0.289-1.885) 0.525	1.474 (0.568-3.824) 0.425	0.642 (0.287-1.433) 0.279	1.705 (0.762-3.813) 0.194*	2.263 (0.922-5.554) 0.075*
Age						
20-30	Ref	Ref	Ref	Ref	Ref	Ref
30-40	0.992 (0.338-2.913) 0.989	0.6 (0.203-1.776) 0.356	0.436 (0.14-1.354) 0.151*	0.588 (0.237-1.46) 0.253	1.038 (0.418-2.581) 0.935	1.078 (0.403-2.888) 0.881
40-50	1.303 (0.245-6.938) 0.757	It cannot be calculated	0.227 (0.027-1.933) 0.175*	0.306 (0.072-1.291) 0.107*	0.281 (0.066-1.19) 0.085*	1.176 (0.273-5.063) 0.827
More than 50	1.447 (0.153-13.725) 0.747	2.5 (0.449-13.907) 0.295	1.133 (0.187-6.876) 0.892	0.815 (0.149-4.444) 0.813	0.15 (0.016-1.382) 0.094*	2.206 (0.237-20.542) 0.487
Education level						
B.Sc. in pharmacy	Ref	Ref	Ref	Ref	Ref	Ref
Diploma	0.882 (0.154-5.071) 0.888	0.905 (0.094-8.716) 0.931	0.755 (0.08-7.133) 0.806	0.548 (0.116-2.578) 0.446	2.28 (0.413-12.579) 0.344	2.625 (0.291-23.639) 0.389
Masters	0.588 (0.124-2.785) 0.504	1.81 (0.302-10.858) 0.517	2.643 (0.531-13.145) 0.235	0.114 (0.013-0.991) 0.049	0.38 (0.084-1.718) 0.209	0.3 (0.069-1.308) 0.109*
Pharm.D	1.275 (0.41-3.96) 0.675	3.8 (1.24-11.642) 0.019*	2.403 (0.799-7.222) 0.119*	0.806 (0.324-2.006) 0.642	0.591 (0.236-1.481) 0.262	0.825 (0.304-2.241) 0.706
Ph.D	It cannot be calculated	6.333 (0.745-53.87) 0.091*	5.286 (0.635-44.033) 0.124*	It cannot be calculated	0.76 (0.098-5.896) 0.793	It cannot be calculated

Continued

Table IV *(Continued)*. Univariate logistic regression model examining factors affecting the knowledge, awareness, and practice of pharmacists towards reporting ADRs.

Dependent factors Independent factors	Are you familiar with the ADRs reporting system in Saudi Arabia? (Ref = No)	How often do you report ADRs that you encounter? (Ref = negative or reluctant attitude)	How often do you discuss ADR with the prescriber if you encounteranу? (Ref = negative or reluctant attitude)	How often do you counsel your patients about ADRs associated with their medications? (Ref = negative or reluctant attitude)	How often do you ask your patients if they are allergic to medications? (Ref = negative or reluctant attitude)	When dispensing medications, how often do you ask a female patient if she is pregnant/ lactating? (Ref = negative or reluctant attitude)
	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value
Years of experience (as a pharmacist)						
< 1	Ref	Ref	Ref	Ref	Ref	Ref
1-3	4.9 (1.179-20.373) 0.029*	0.717 (0.204-2.525) 0.605	0.476 (0.136-1.669) 0.246	0.618 (0.188-2.029) 0.427	0.308 (0.082-1.149) 0.08*	0.587 (0.154-2.237) 0.435
4-6	2.567 (0.518-12.723) 0.248	0.141 (0.015-1.357) 0.09*	0.11 (0.012-1.044) 0.055*	0.28 (0.062-1.266) 0.098*	0.123 (0.025-0.617) 0.011*	0.41 (0.088-1.917) 0.257
7-9	6.3 (0.644-61.631) 0.114*	0.204 (0.021-2.018) 0.174*	0.357 (0.058-2.217) 0.269	0.7 (0.145-3.37) 0.656	0.205 (0.038-1.112) 0.066*	1.231 (0.182-8.33) 0.831
More than 9	2.1 (0.552-7.993) 0.277	0.611 (0.157-2.375) 0.477	0.376 (0.095-1.494) 0.165*	0.7 (0.2-2.454) 0.577	0.364 (0.092-1.443) 0.15*	1.169 (0.263-5.199) 0.837
Type of pharmacy						
Community pharmacy	Ref	Ref	Ref	Ref	Ref	Ref
Hospital pharmacy	2.462 (0.917-6.607) 0.074*	3.046 (1.02-9.095) 0.046*	1.339 (0.504-3.56) 0.558	0.632 (0.277-1.445) 0.277	0.655 (0.286-1.498) 0.316	0.621 (0.245-1.571) 0.314
Primary medical center	It cannot be calculated	It cannot be calculated	It cannot be calculated	It cannot be calculated	It cannot be calculated	It cannot be calculated
Outpatient pharmacy	It cannot be calculated	It cannot be calculated	It cannot be calculated	It cannot be calculated	It cannot be calculated	It cannot be calculated
Do you have internet service in the pharmacy? (Ref=No)	2.656 (0.766-9.207) 0.123*	0.658 (0.182-2.375) 0.522	1.042 (0.261-4.159) 0.954	0.35 (0.1-1.226) 0.101*	0.273 (0.07-1.062) 0.061*	0.406 (0.084-1.961) 0.262
Have you taken any continuing medical education (CME) about ADRs? (Ref=No)	1.25 (0.474-3.297) 0.652	1.252 (0.482-3.252) 0.644	2.684 (0.952-7.567) 0.062*	0.986 (0.441-2.204) 0.973	1.32 (0.59-2.953) 0.499	0.793 (0.324-1.94) 0.612

Continued

Table IV *(Continued)*. Univariate logistic regression model examining factors affecting the knowledge, awareness, and practice of pharmacists towards reporting ADRs.

Dependent factors Independent factors	Are you familiar with the ADRs reporting system in Saudi Arabia? (Ref = No)	How often do you report ADRs that you encounter? (Ref = negative or reluctant attitude)	How often do you discuss ADR with the prescriber if you encounteranу? (Ref = negative or reluctant attitude)	How often do you counsel your patients about ADRs associated with their medications? (Ref = negative or reluctant attitude)	How often do you ask your patients if they are allergic to medications? (Ref = negative or reluctant attitude)	When dispensing medications, how often do you ask a female patient if she is pregnant/ lactating? (Ref = negative or reluctant attitude)
	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value
How many prescriptions, on average, do you dispense in one month?						
1-10	Ref	Ref	Ref	Ref	Ref	Ref
11-20	2.222 (0.473-10.447) 0.312	It cannot be calculated	1.444 (0.118-17.671) 0.773	0.833 (0.179-3.884) 0.816		1.296 (0.303-5.54) 0.726
More than 20	2.84 (0.769-10.481) 0.117*	1.784 (0.442-7.2) 0.416	6.324 (0.766-52.19) 0.087*	3.478 (0.97-12.477) 0.056*	1.286 (0.394-4.197) 0.677	1.242 (0.362-4.265) 0.731

*: Significant *p*-value (lower than or equal to 0.20).

Table V. Multivariate logistic regression model examining factors affecting the knowledge, awareness, and practice of pharmacists towards reporting ADRs (only variables with a *p*-value equal to or less than 0.2 in the univariate model).

Dependent factors Independent factors	Are you familiar with the ADRs reporting system in Saudi Arabia? (Ref = No)	How often do you report ADRs that you encounter? (Ref = negative or reluctant attitude)	How often do you discuss ADR with the prescriber if you encounteranу? (Ref = negative or reluctant attitude)	How often do you counsel your patients about ADRs associated with their medications? (Ref = negative or reluctant attitude)	How often do you ask your patients if they are allergic to medications? (Ref = negative or reluctant attitude)	When dispensing medications, how often do you ask a female patient if she is pregnant/ lactating? (Ref = negative or reluctant attitude)
	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value
Sex (Ref = female)	NA	NA	NA	NA	2.968 (1.047-8.414) 0.041*	3.217 (1.171-8.838) 0.023*
Age						
20-30	NA	NA	Ref	Ref	Ref	NA
30-40	NA	NA	0.226 (0.009-5.431) 0.359	0.165 (0.02-1.354) 0.093	1.002 (0.189-5.32) 0.998	NA
40-50	NA	NA	0.034 (0-2.89) 0.135	0.061 (0.004-0.851) 0.038*	0.16 (0.015-1.716) 0.13	NA
More than 50	NA	NA	0.061 (0.001-5.853) 0.23	0.126 (0.007-2.323) 0.163	0.069 (0.003-1.45) 0.085	NA
Education level						
B.Sc. in pharmacy	NA	Ref	Ref	NA	NA	Ref
Diploma	NA	0.674 (0.063-7.199) 0.744	0.507 (0.037-6.916) 0.611	NA	NA	3.258 (0.343-30.906) 0.304
Masters	NA	1.661 (0.233-11.835) 0.613	7.741 (0.642-93.31) 0.107	NA	NA	0.232 (0.049-1.085) 0.063
Pharm.D	NA	2.186 (0.619-7.726) 0.225	1.403 (0.352-5.591) 0.632	NA	NA	1.115 (0.385-3.23) 0.841
Ph.D	NA	5.784 (0.574-58.244) 0.136	10.098 (0.652-156.273) 0.098	NA	NA	It cannot be calculated

Continued

Table V *(Continued)*. Multivariate logistic regression model examining factors affecting the knowledge, awareness, and practice of pharmacists towards reporting ADRs (only variables with a *p*-value equal to or less than 0.2 in the univariate model).

Dependent factors Independent factors	Are you familiar with the ADRs reporting system in Saudi Arabia? (Ref = No)	How often do you report ADRs that you encounter? (Ref = negative or reluctant attitude)	How often do you discuss ADR with the prescriber if you encounteranу? (Ref = negative or reluctant attitude)	How often do you counsel your patients about ADRs associated with their medications? (Ref = negative or reluctant attitude)	How often do you ask your patients if they are allergic to medications? (Ref = negative or reluctant attitude)	When dispensing medications, how often do you ask a female patient if she is pregnant/ lactating? (Ref = negative or reluctant attitude)
	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value
Years of experience (as a pharmacist)						
< 1	Ref	Ref	Ref	Ref	Ref	NA
1-3	4.786 (0.966-23.698) 0.055	0.695 (0.172-2.8) 0.608	0.913 (0.207-4.028) 0.905	0.961 (0.264-3.495) 0.951	0.261 (0.064-1.07) 0.062	NA
4-6	2.176 (0.363-13.046) 0.395	0.171 (0.015-1.904) 0.151	0.199 (0.008-5.27) 0.334	1.27 (0.155-10.376) 0.823	0.119 (0.016-0.908) 0.04*	NA
7-9	4.51 (0.419-48.61) 0.214	0.295 (0.024-3.559) 0.337	2.177 (0.045-105.047) 0.694	5.892 (0.391-88.719) 0.2	0.26 (0.022-3.012) 0.281	NA
More than 9	1.752 (0.377-8.135) 0.474	0.562 (0.103-3.076) 0.506	2.441 (0.052-114.768) 0.65	7.211 (0.552-94.105) 0.132	0.609 (0.053-6.968) 0.69	NA
Type of pharmacy						
Community pharmacy	Ref	Ref	NA	NA	NA	NA
Hospital pharmacy	2.566 (0.833-7.907) 0.101	3.201 (0.938-10.924) 0.063	NA	NA	NA	NA
Primary medical center	It cannot be calculated	It cannot be calculated	NA	NA	NA	NA
Outpatient pharmacy	It cannot be calculated	It cannot be calculated	NA	NA	NA	NA
Do you have internet service in the pharmacy? (Ref = No)	2.531 (0.537-11.932) 0.241	NA	NA	0.557 (0.137-2.276) 0.416	0.406 (0.091-1.813) 0.238	NA
Have you taken any continuing medical education (CME) about ADRs? (Ref = No)	NA	NA	4.757 (1.268-17.844) 0.021*	NA	NA	NA

Continued

Table V *(Continued)*. Multivariate logistic regression model examining factors affecting the knowledge, awareness, and practice of pharmacists towards reporting ADRs (only variables with a *p*-value equal to or less than 0.2 in the univariate model).

Dependent factors Independent factors	Are you familiar with the ADRs reporting system in Saudi Arabia? (Ref = No)	How often do you report ADRs that you encounter? (Ref = negative or reluctant attitude)	How often do you discuss ADR with the prescriber if you encounteranу? (Ref = negative or reluctant attitude)	How often do you counsel your patients about ADRs associated with their medications? (Ref = negative or reluctant attitude)	How often do you ask your patients if they are allergic to medications? (Ref = negative or reluctant attitude)	When dispensing medications, how often do you ask a female patient if she is pregnant/ lactating? (Ref = negative or reluctant attitude)
	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value	OR (95% CI) *p*-value
How many prescriptions, on average, do you dispense in one month?						
1-10	Ref	NA	Ref	Ref	NA	NA
11-20	2.329 (0.434-12.497) 0.324	NA	2.542 (0.181-35.68) 0.489	1.269 (0.245-6.563) 0.776	NA	NA
More than 20	3.384 (0.765-14.965) 0.108	NA	11.61 (1.233-109.315) 0.032*	3.671 (0.96-14.039) 0.057	NA	NA

*: Significant p-value (lower than 0.05).

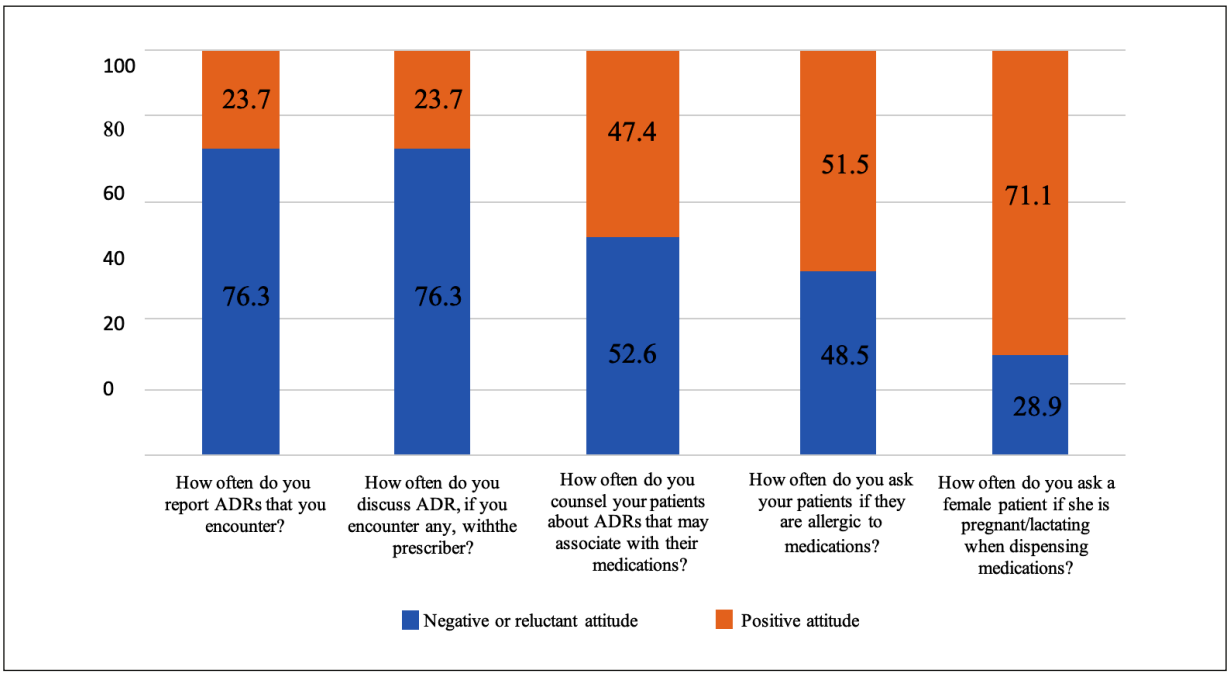

Figure 1. Pharmacists' attitude towards reporting ADRs.

unit received 187 suspected ADR reports between April 2016 and August 2020. Anti-infective agents were the most reported medication classes (36.73%)[23].

In contrast to NPC-SFDA, the most often reported[24] medication classes in Turkey's ADRs database from 2005 to 2013 were antineoplastic and immunomodulating medicines (21.49%), followed by anti-infective agents for systemic use (22.27%). Therefore, it is evident that there are regional variations in the medications that are reported for ADRs. Pharmacovigilance training programs for pharmacists should concentrate on these essential drug classes and drugs most frequently associated with ADRs.

An open-label randomized controlled study[16] in Saudi Arabia showed that ADR-specific education can increase pharmacists' knowledge and awareness of ADRs and their reporting procedures. According to this study, future research should develop effective training techniques for delivering pharmacovigilance education to healthcare workers to enhance ADR reporting in Saudi Arabia[16]. In support of this study, many investigations[25,26] have demonstrated that pharmacists with continually improving therapeutic expertise are more likely to report ADRs. Appropriate training for pharmacists regarding ADR reporting, before they are awarded a license, would be one method to raise knowledge about the Saudi ADR reporting system among foreign pharmacists.

Limitations

Furthermore, this study has some limitations, as the findings of this study may not apply to pharmacist opinion in other regions due to variances in practice and understanding across pharmacies in different cities. The well-developed and evaluated questionnaire utilized to target the study's goal sets it apart from others. The study was done among a cohort of Saudi Arabian pharmacists with a representative sample size. However, the form of this study (a questionnaire-based survey) limits it, and further prospective qualitative studies may be conducted to delve deeper into the encouraging variables. Furthermore, the study employed in this study requires additional reliability and validity assessments. Moreover, because this study included both hospital and community pharmacists, further studies focusing on pharmacists from various practice settings are required to provide greater clarification. In addition, the findings of this study cannot be applied to other regions of Saudi Arabia.

Overall, this study's results highlight the need to improve pharmacist awareness to overcome the underreporting. This recommendation is similar to the opinion shared by experts of other sim-

ilar studies[27,28] conducted in Saudi Arabia. Pharmacovigilance authorities in Saudi Arabia should implement into practice interventional programs that have been shown[29,30] to raise ADR reporting knowledge and awareness in other nations. Pharmacy students participating in community pharmacy internships may increase future pharmacists' understanding of ADR identification and reporting[31,32]. Furthermore, continuing education/training programs in pharmacovigilance and spontaneous reporting may reduce the prevalence of underreporting.

Moreover, pharmacists will be more likely to report adverse drug reactions (ADRs) if therapeutic understanding regarding ADRs improves. All hospitals should employ medication safety officers responsible for all aspects of drug safety, including ADR reporting. Universities should urge health colleges to include pharmacovigilance in their curriculum. A collaboration between regulatory bodies and pharmaceutical firms should be enhanced to apply monitoring and reporting rules.

Conclusions

Although pharmacists are aware of the need to report adverse drug reactions, many are unable to do so because of the demanding job environment. As a result, comprehensive and ongoing training for pharmacists is required to raise awareness of the need for ADR reporting and measures to overcome stress.

Conflict of Interest
The Authors declare that they have no conflict of interests.

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Informed Consent
Written informed consent was obtained from the participants of the study.

Ethics Approval
The Deanship of Scientific Research of King Khalid University provided institutional ethical approval (no. ECM#2021-5711, dated 19.09.2021).

Availability of Data and Materials
The data presented and supporting the findings of this study are available upon reasonable request from the corresponding author (A.Y).

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Authors' Contribution
Conceptualization: A.Y., and O.K.; data curation: O.K., C.K., A.R.N.I., and V.K.; formal analysis: A.Y., A.A., and V.K.; methodology: A.Y., A.M.K.I., A.A.I.M., S.A.S., and O.K.; supervision: A.Y., O.K., and A.A.; softwares and validation: A.Y., A.M.K.I., A.A.I.M., A.R.N.I., and S.A.S.; writing-original draft: A.Y., V.K., and O.K.; funding: A.R.NI.; writing-review and editing: A.Y., A.A., and C.K. All authors have read and agreed to the published version of the manuscript in ERMPS.

ORCID ID
Yahia Alghazwani: 0000-0002-4275-2134; Ali Alqahtani: 0000-0002-2240-4757; Kumarappan Chidambaram: 0000-0002-7981-4562; Krishnaraju Venkatesan: 0000-0003-2853-5907.

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