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Knowledge, Attitude, And Practice Of Pharmacists Toward Adverse Drug Even Reporting: A Cross- Sectional Study.

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ABSTRACT

Adverse Drug Reactions (ADRs) pose a significant threat to patient health globally, contributing to increased morbidity and mortality. This study focuses on evaluating the knowledge, attitude, and practice (KAP) of ADR reporting among hospital pharmacists in Saudi Arabia, recognizing their pivotal role in ensuring drug safety within medical institutions. A multi-center, cross-sectional study was conducted through a questionnaire survey distributed to hospital pharmacists in various regions of Saudi Arabia. The questionnaire comprised 25 mandatory single-choice items and one multiple-choice item addressing pharmacist characteristics, knowledge, attitudes, and practices related to ADR reporting. Descriptive statistics, one-way ANOVA, and ordinal logistic regression were employed for data analysis. A total of 345 valid questionnaires were analyzed, revealing that 10.6% of pharmacists lacked a clear understanding of the basic definition of ADR. Furthermore, 58.5% exhibited misconceptions about the reporting time for new and serious adverse reactions. Pharmacists with lower academic qualifications, professional titles, and those without training demonstrated limited basic knowledge. While the majority displayed positive attitudes towards ADR reporting, variations were observed based on age, gender, and training participation. Dispensing pharmacists exhibited lower ADR reporting practice scores compared to clinical pharmacists. Knowledge and attitude were identified as predictors of pharmacists' ADR reporting practices. Despite positive attitudes, hospital pharmacists in Saudi Arabia demonstrated gaps in knowledge and practices related to ADR reporting. Training significantly influenced knowledge, attitude, and practice scores. Strengthening education and continuous professional development programs, particularly focusing on dispelling misconceptions and enhancing reporting practices, are crucial for improving ADR reporting among pharmacists.

Keywords: Adverse Drug Reactions, Hospital Pharmacists, Knowledge, Attitude, Practice, Saudi Arabia.

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INTRODUCTION

The World Health Organization (WHO) characterizes adverse drug reactions (ADRs) as harmful effects unrelated to the intended purpose of medication, occurring when normal drug doses are used for prevention, diagnosis, treatment, or physiological regulation [1,2]. ADRs significantly impact patient health and pose a major global challenge, contributing to increased morbidity and mortality [3]. Approximately 5% of hospitalized patients experience ADRs, with a similar percentage encountering ADRs during hospitalization [4]. In the European Union, ADRs cause an estimated 197,000 deaths annually [5]. In the United States, adverse drug events incur substantial costs, with estimates of \$19,685 and \$13,994 for ICU and non-ICU ward hospitalizations, respectively [6]. Vigilant monitoring of ADRs is crucial for global healthcare.

In all nations, national pharmacovigilance systems heavily rely on spontaneous reporting, where health professionals, pharmaceutical producers, or individuals report suspected ADRs to a national coordinating center [7]. Although spontaneous reports have advantages in identifying potential safety signals, they suffer from drawbacks such as underreporting, poor report quality, challenges in quantifying risk, and unknown exposure figures [8,9].

In Saudi Arabia, the Saudi Food and Drug Authority (SFDA) has implemented pharmacovigilance initiatives to oversee the risk-benefit equilibrium of all registered products throughout their active marketing cycle [8]. The SFDA actively monitors and evaluates spontaneous adverse drug reaction (ADR) reports at the national level, originating from both healthcare professionals and the general public [8,10]. This comprehensive approach encompasses post-marketing surveillance of drugs and medical products, ADR signal detection, receipt of notifications related to drug safety and quality, ongoing safety updates, and the formulation of appropriate recommendations through the deliberations of the Pharmacovigilance Advisory Committee. In 2015, the SFDA instituted the second edition of the Saudi Pharmacovigilance Guidelines on Good Pharmacovigilance Practices (GVP), effectively implementing these guidelines nationwide [8,11].

A majority of ADR reports in Saudi Arabia originate from healthcare professionals (82.7%) [12]. In a previous study, in Riyadh, Mahmoud M et al reported that most of the community pharmacists had poor knowledge, attitude, and practice toward ADR reporting [12]. A survey conducted in three provinces in China revealed that pharmacists accounted for the largest proportion of ADR reports (41.2%) from all sources during 2015–2017, yet only 13.8% of these reports demonstrated high quality [13]. Another study indicated that hospital pharmacists in a northern region of China exhibit good knowledge and attitudes but demonstrate poor practices regarding ADR reporting [14]. To comprehend the challenges faced by pharmacists in reporting ADRs and to provide recommendations for enhancing the rate and quality of ADR reporting, this survey explores pharmacists' knowledge, perceptions, and practices related to ADR reporting in Saudi Arabia.

METHODOLOGY

This research, conducted in Saudi Arabia, adopted a multicenter, cross-sectional approach through a questionnaire survey distributed to hospital pharmacists by online distributed questionnaire. The questionnaire, facilitated by the Google sheet, was disseminated in Facebook and WhatsApp groups across various provinces in Saudi Arabia. From October to November 2023, 386 individuals participated, with exclusion criteria based on pharmacists not working in hospitals or providing invalid responses (questionnaire completion time less than 1 minute or exceeding 1 hour). Ultimately, 345 valid questionnaires were collected in Saudi Arabia, achieving an effective rate of 89.4%. All participants' responses were anonymous and voluntary.

The self-administered questionnaire comprised 25 mandatory single-choice items and one multiple-choice item. Developed with reference to scientific literature and the authors' practical experience [15], the questionnaire underwent content validity assessment by two pharmacovigilance experts. It encompassed five main parts: (i) Pharmacist characteristics, including education, professional rank, and work experience; (ii) Knowledge, assessed through multiple-choice questions on ADR definition, reporting time, etc.; (iii) Attitudes, gauged on a 5-level Likert scale reflecting pharmacists' concerns and willingness towards ADR reporting; (iv) Practice, involving two items on ADR reporting based on the surveyors' experience; (v) Investigating influencing factors for ADR reporting.

Statistical analysis utilized SPSS 28.0 and Microsoft Excell for entering, cleaning and coding the data. Descriptive statistics, using percentages or frequencies, were employed for demographic variables while mean and standard deviation were used for description of ongoing variables. One-way ANOVA explored the relationships between pharmacists' characteristics and knowledge and attitude scores. Ordinal logistic regression analyzed the correlation between knowledge, attitude, and practice, with covariates identified from single-factor analysis results with $p < 0.05$.

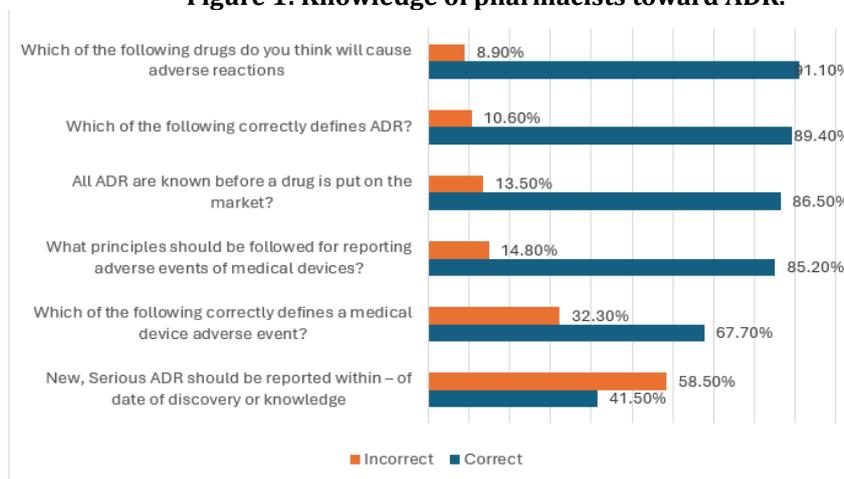
RESULTS

A total of 386 questionnaires were collected, and 345 of them were valid and included in the analysis, resulting in an effective rate of 89.4%. Among the respondents, 113 (32.8%) were males, and 232 (67.2%) were females. Additionally, 159 pharmacists (46.1%) were under the age of 35, and 173 pharmacists (50.1%) were from non-tertiary medical institutions. The educational background of 285 pharmacists (82.6%) was college degrees, and 200 pharmacists (58.0%) held intermediate professional titles. Furthermore, 283 pharmacists (82.0%) had more than 6 years of work experience, and 259 pharmacists (75.1%) had participated in ADR training before. In addition, 278 participants were dispensing pharmacists (80.6 %) while 19.4 % of them were clinical ones. The characteristics of the included pharmacists are detailed in Table 1.

Table 1: Characteristics of Pharmacists.

Variables	N	Percentage (%)
Gender	Male	113 32.8 %
	Female	232 67.2 %
Age (years)	≤35	159 46.1 %
	36-45	101 29.3 %
	>45	85 24.6 %
Type of Medical institution	Tertiary hospital	172 49.9 %
	Non-tertiary hospital	173 50.1 %
Education	College degree	285 82.6 %
	Master's degree and above	60 17.4 %
Professional rank	Junior	79 23.0 %
	Intermediate	200 58.0 %
	Senior	66 19.1 %
Years of working	≤5	64 18.6 %
	6-20	155 44.9 %
	>20	126 36.5 %
Training attending	Yes	259 75.1 %
	No	86 24.9 %
Types of Pharmacists	Clinical pharmacist	67 19.4 %
	Dispensing pharmacist	278 80.6 %

Figure 1: Knowledge of pharmacists toward ADR.



The findings regarding pharmacists' attitudes towards adverse drug reaction (ADR) reporting indicated a predominantly positive stance. Specifically, 95.4% of pharmacists agreed that monitoring adverse drug reactions is beneficial to public health, while 83.2% believed that reporting adverse drug reactions was a part of their professional responsibilities. Moreover, 90.1% disagreed with the notion that only serious adverse drug reactions should be reported, and an overwhelming 95.6% expressed a willingness to participate in adverse drug reaction reporting training. In addressing concerns about whether adverse drug reaction reports generate additional workload, 49.0% of pharmacists believed that ADR reporting would indeed result in increased workload. Detailed results can be found in Table 2.

Table 2: Attitudes of Pharmacists towards ADR.

Items	Strongly agree (%)	Agree (%)	Neutral (%)	Disagree (%)	Strongly disagree (%)
You will pay attention to the possible ADR of patients	37.1 %	48.4 %	11.3 %	0.6 %	2.6 %
Monitoring of ADR is considered beneficial to public health	60.3 %	35.1 %	1.7 %	0.9 %	2.0 %
Reporting an ADR report can also have an impact on public health	37.1 %	48.4 %	11.3 %	0.6 %	2.6 %
Reporting ADR is as part of my responsibilities	34.8 %	48.4 %	11.3 %	0.6 %	2.6 %
Only serious ADR should be reported	1.2 %	3.8 %	4.9 %	61.4 %	28.7 %
ADR report will generate extra workload	13.9 %	35.1 %	22.0 %	23.2 %	5.8 %
Are you willing to participate in the training of ADR reports?	39.1 %	56.5 %	4.4 %	0.3 %	0.6 %
Monitoring of adverse drug reactions should protect patient privacy	38.3 %	56.8 %	4.9 %	0.4 %	0.6 %
Adverse drug reactions should be reported regularly	39.1 %	56.5 %	4.4 %	0.3 %	0.6 %

Table 3: The Relation between the Pharmacist's Characteristics and KAP

Variable		Knowledge score (0-6)		Attitude score (0-45)	
		Mean (SD)	P-value	Mean (SD)	P-value
Gender	Male	4.64 (1.23)	0.321	35.89 (4.25)	0.023*
	Female	4.58 (1.21)		36.46 (3.52)	
Age (years)	≤35	4.32 (1.25)	0.712	36.50 (3.1)	0.001*
	36-45	4.25 (1.12)		36.64 (2.85)	
	>45	4.26 (1.19)		35.75 (2.83)	
Type of hospital	Tertiary	4.35 (1.21)	0.132	36.58 (3.04)	0.012*
	Non-tertiary	4.24 (1.01)		36.01 (2.89)	
Education background	College degree	4.28 (1.25)	0.000*	35.34 (3.10)	0.004*
	Master's degree and above	4.81 (1.02)		36.52 (2.89)	
Professional rank	Junior	4.41 (1.13)	0.000*	37.25 (2.64)	0.988
	Intermediate	4.35 (1.02)		37.21 (3.01)	
	Senior	4.51 (1.01)		37.27 (2.89)	
Working years	≤5	4.27 (1.27)	0.574	36.52 (3.06)	0.021*
	6-20	4.32 (1.32)		36.46 (3.05)	
	>20	4.26 (1.02)		35.81 (2.75)	
Training attending	Yes	4.32 (1.25)	0.012*	36.52 (3.05)	0.001*
	No	4.14 (0.95)		35.31 (2.63)	
Type of pharmacist	Clinical pharmacist	4.95 (1.05)	0.000*	36.41 (3.05)	0.342
	Dispensing pharmacist	4.32 (1.25)		36.25 (2.95)	

The investigation revealed notable distinctions between pharmacists' characteristics and their scores in adverse drug reaction (ADR) knowledge. Education, professional title, training participation, and job type demonstrated statistically significant variances in ADR knowledge scores ($p < 0.05$). Pharmacists with college education, holding junior professional titles, those without training participation, and dispensing pharmacists displayed comparatively lower knowledge scores. Furthermore, knowledge scores were diminished among pharmacists working in non-tertiary hospitals compared to their counterparts in tertiary hospitals ($p < 0.05$). Significant variations were also identified in pharmacist characteristics and ADR attitude scores. Male pharmacists, those under the age of 35, employed in non-tertiary hospitals, possessing lower educational backgrounds, having less than 5 years of work experience, and those lacking training exhibited relatively lower scores ($p < 0.05$). Detailed insights into the differences in knowledge and attitude scores among pharmacists are outlined in Table 3.

Employing knowledge and attitude scores as predictive factors, this study examined their correlation with pharmacists' practice towards adverse drug reaction (ADR) reporting (Table 4). A significant association was observed for both knowledge [OR (95% CI): 1.54 (1.16, 1.26), $p = 0.001$] and attitude score [OR (95% CI): 1.15 (1.02, 1.26), $p = 0.002$] with the practice scores of pharmacists. The covariates considered in the model encompassed gender, age, hospital grade, educational background, title, working years, training participation, and job type. Furthermore, pharmacist characteristics emerged as significant predictors of practice scores. The results from the multivariate model elucidated that the odds of achieving a higher practice score were 0.61 (95% CI: 0.38-0.98, $p = 0.041^*$) times higher among pharmacists in the age group 36–45 years compared to those older than 45 years. Pharmacists from non-tertiary hospitals exhibited 1.60 (95% CI: 1.21, 2.12) times greater risk of obtaining higher practice scores compared to pharmacists from tertiary hospitals. Moreover, the likelihood of achieving a higher practice score was 3.07 (95% CI: 1.64, 5.76) times higher among pharmacists in the working year group ≤ 5 compared to those with ≥ 20 years of experience. Pharmacists with training experience had 1.81 (95% CI: 1.34, 2.45) times higher practice scores compared to their counterparts with no training experience. Additionally, dispensing pharmacists demonstrated 0.21 (95% CI: 0.14, 0.34) times higher practice scores than clinical pharmacists.

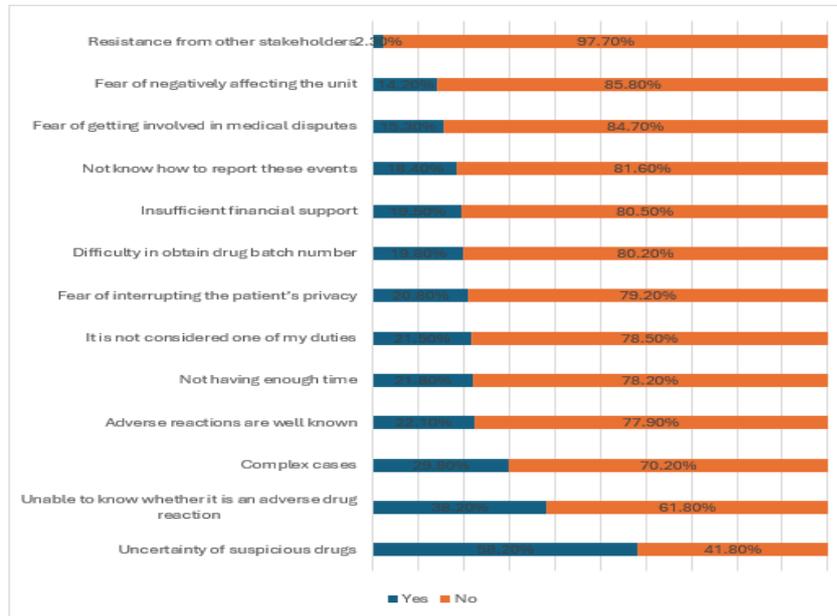
Table 4: Predictors of Pharmacists' Practice Toward ADR Reporting

	Variables	Crude OR (95% CI)	p
Knowledge score		1.54 (1.16, 1.65)	0.001*
Attitude score		1.15 (1.02, 1.26)	0.002*
Gender	Male	1.18 (0.76, 1.81)	0.451
	Female	Reference	
Age (years)	≤ 35	0.92 (0.56, 1.52)	0.741
	36–45	0.61 (0.38, 0.98)	0.041*
	>45	Reference	
Type of hospital	Tertiary	Reference	
	Non-tertiary	1.60 (1.21, 2.12)	0.001*
Education background	College degree	Reference	
	Master's degree and above	0.92(0.61, 2.09)	0.69
Professional rank	Junior	0.98 (0.64, 1.51)	0.92
	Intermediate	Reference	
	Senior	0.58 (0.23, 1.02)	0.83
Working years	≤ 5	3.07 (1.64, 5.76)	0.001*
	6–20	1.73 (1.07, 2.79)	0.025*
	>20	Reference	
Training attending	Yes	1.81 (1.34, 2.45)	<0.001*
	No	Reference	
Type of pharmacist	Clinical pharmacist	Reference	
	Dispensing pharmacist	0.21 (0.14, 0.34)	<0.001*

Our study delved into the factors influencing pharmacists' adverse drug reaction (ADR) reporting (Figure 2). The investigation revealed that the top three primary factors impacting pharmacists' ADR reporting included uncertainty regarding the suspected drug, the challenge in determining whether it

constituted an adverse drug reaction, and the complexity of the reporting process. Additionally, 18.4% of respondents expressed a lack of knowledge on how to execute the reporting procedure.

Figure 2: Factors influencing the reporting of ADR among pharmacists.



DISCUSSION

Medications serve as the primary treatment for various diseases, underscoring the importance of ensuring their rational use [16,17]. Inadequate attention to drug safety can lead to severe consequences, ranging from lifelong disabilities to fatal outcomes [18]. Timely reporting of Adverse Drug Reactions (ADRs) plays a crucial role in enhancing drug safety and preventing potential harm associated with medication use [19]. This study focuses on assessing and comparing the variances in knowledge, attitude, and practice related to ADR reporting among pharmacists with diverse characteristics in Saudi Arabia. Given that numerous serious ADRs occur within hospital settings or result in hospitalization, pharmacists within medical institutions are pivotal contributors to the ADR reporting process [20,21]. Moreover, since most novel drugs are initially introduced and utilized in hospitals, understanding the knowledge, attitude, and practice of hospital pharmacists in the ADR reporting process is particularly pertinent.

The study identified that 10.6% of pharmacists exhibited uncertainty regarding the fundamental definition of ADR, aligning with findings from previous research [14]. However, our results are better than reported in some previous studies reported that only lower than two thirds of the pharmacists had knowledge considering definition of ADR in Najran, Saudi Arabia [21], Jordan [22], Syria [23], and Saudi Arabia [24]. Additionally, 58.5% of pharmacists displayed misconceptions about the reporting timeframe for new and serious adverse reactions, indicating a gap in their foundational knowledge of ADR reporting. Pharmacists with lower academic qualifications, professional titles, and those without training demonstrated limited basic knowledge in ADR reporting similar to what reported in previous study [15]. Educational background, professional title, and participation in training were found to be correlated with basic knowledge related to ADR reporting, emphasizing the need for improved education among certain pharmacists. Approximately 32.3% of pharmacists exhibited poor knowledge regarding medical device adverse events, suggesting a necessity for targeted training to enhance the quality of ADR reporting.

Pharmacists' attitudes play a pivotal role in encouraging timely ADR reporting. The study revealed a predominantly positive attitude among pharmacists, with the majority acknowledging ADR reporting as part of their responsibilities which is consistent with the results of previous similar studies [25–27]. Although most pharmacists displayed consistent attitudes towards ADR reporting, male pharmacists and those under 35 years of age exhibited slightly lower positive attitudes, potentially linked to their relatively short length of service. Pharmacists with more extensive work experience and exposure to adverse events demonstrated a more positive attitude towards ADR reporting. Participation in ADR

training was associated with higher positive attitudes, underscoring the importance of continuous education in this domain.

Significant differences were observed in pharmacist characteristics and ADR practice scores. Factors such as education level, age, years of experience, and ADR training were found to influence practice scores. Pharmacists with lower education levels, aged over 45, and those with less than 5 years of experience or lacking ADR training exhibited lower practice scores. Dispensing pharmacists demonstrated lower ADR reporting practice scores than clinical pharmacists, potentially influenced by the nature of their work responsibilities.

The study highlighted the positive impact of both knowledge and attitude on pharmacists' ADR reporting practices. Future strategies aimed at enhancing ADR reporting should focus on improving pharmacists' knowledge and fostering positive attitudes. Continuous professional development plans can address knowledge and skill gaps in detecting and reporting ADRs, with an emphasis on changing attitudes and perspectives on ADR reporting. The study identified factors such as uncertainty about suspected drugs, difficulty in determining adverse drug reactions, and the complexity of reporting as significant challenges in ADR reporting. Providing ongoing education to healthcare professionals, especially pharmacists, has been proven to alter behavior and attitudes towards ADR reporting. Evidence suggests that continuous education for health professionals can effectively alter their behaviors and attitudes towards adverse drug reaction (ADR) reporting [28,29]. The purpose of such educational initiatives should extend beyond merely enhancing pharmacists' knowledge of ADR to include efforts directed at transforming their attitudes and perspectives on ADR reporting. Our study results further reinforce the notion that pharmacists who have undergone ADR training exhibit higher knowledge, attitude, and practice scores. As experts, pharmacists assume a crucial role in ensuring drug safety through the detection and reporting of ADRs [20]. Over the past decades, the global role of pharmacists has evolved from mere dispensers to becoming guardians of drug safety [14,20,30]. Research findings indicate that hospital pharmacists not only possess the capability to detect and report ADRs but can also contribute to the prevention of ADR-related incidents. Moreover, pharmacists with a clinical background, working closely with prescribers and patients, are better equipped to comprehend suspicious ADRs [15]. Consequently, comprehensive training and education on ADR are of paramount importance. Despite the insightful findings, the study has limitations. It primarily focuses on a single province in Saudi Arabia, and generalizing the conclusions to other regions requires further research. The reliance on self-assessment for ADR knowledge, attitudes, and practices may introduce social expectation bias, as participants may be hesitant to disclose practice flaws. The study mitigates this bias through anonymity but acknowledges the potential influence of hospital administrators on participants. Notwithstanding these limitations, the research results are deemed reliable, offering valuable insights to enhance ADR reporting among pharmacists in Saudi Arabia.

CONCLUSION

In conclusion, while hospital pharmacists in Saudi Arabia generally exhibit positive attitudes towards ADR reporting, gaps in knowledge and practice persist. The study underscores the importance of strengthening training and education programs for pharmacists, with a specific focus on improving knowledge and fostering positive attitudes towards ADR monitoring. The findings emphasize the crucial role of pharmacists in ensuring drug safety through the detection and reporting of ADRs. Continuous efforts should be made to elevate the role of pharmacists from mere dispensers to guardians of drug safety, aligning with the evolving global trend in pharmaceutical care.

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