

# Pharmacovigilance in Practice: Insights into Knowledge, Attitudes, and Practices of Pharmacists and Pharmacy Technicians in Saudi Arabia

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## ABSTRACT

**Objective:** This study evaluated pharmacists' and pharmacy technicians' knowledge, attitudes, and practices (KAPs) regarding pharmacovigilance and adverse drug reaction (ADR) reporting at a tertiary care facility in Saudi Arabia. It also sought to identify the barriers to ADR reporting and propose strategies to improve pharmacovigilance practices. This study is timely given recent initiatives by the Saudi Vision 2030 to strengthen medication safety practices nationwide.

**Methods:** A cross-sectional survey was conducted among pharmacists and pharmacy technicians at a tertiary care hospital in Saudi Arabia. A structured, self-administered questionnaire collected data on participants' KAPs regarding pharmacovigilance. Descriptive and inferential statistical analyses were conducted to identify the trends and associations between demographic variables and KAP scores. **Findings:** A total of 200 healthcare professionals participated in the study. While 87% of participants were aware of pharmacovigilance and 91% were familiar with ADRs, only 47.5% had ever reported an ADR. Positive attitudes were observed, with 94% agreeing that ADR reporting is an essential role of pharmacists and 90% supporting its inclusion in pharmacy curricula. However, key barriers to ADR reporting included lack of time (65%), insufficient training (58%), and uncertainty about reporting procedures (49%). Significant associations were found between knowledge levels, age, gender, and educational qualifications ( $P < 0.05$ ). **Conclusion:** Despite high levels of knowledge and positive attitudes, ADR reporting practices remain suboptimal due to structural and procedural barriers. To enhance pharmacovigilance practices in Saudi Arabia, targeted training programs, simplified reporting systems, and mandatory reporting policies are recommended.

**KEYWORDS:** Adverse drug reaction reporting, attitudes and practices, knowledge, pharmacists, pharmacovigilance, Saudi Arabia

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## INTRODUCTION

**P**harmacovigilance, defined by the World Health Organization as the science and activities related to detecting, assessing, understanding, and preventing adverse drug reactions (ADRs) or any other drug-related problems, is a cornerstone of modern healthcare systems.<sup>[1]</sup> It plays a critical role in ensuring patient safety by monitoring the risk-benefit balance of medicines throughout their life cycle. ADRs are a significant global public health concern, contributing to substantial morbidity and mortality worldwide. Recent estimates suggest that ADRs account for 5%–10% of hospital admissions in developed countries and are among the leading causes of prolonged hospital stays and healthcare costs.<sup>[2,3]</sup> In the Kingdom of Saudi Arabia (KSA), where the healthcare system is rapidly evolving, pharmacovigilance is increasingly recognized as an essential component of public health. However, its implementation faces challenges, including underreporting ADRs, limited awareness among healthcare professionals, and a lack of robust reporting systems.<sup>[4]</sup>

The rapid expansion of pharmaceutical markets and accelerated drug approvals has heightened the need for comprehensive pharmacovigilance systems. Over the past decade, developing novel therapeutics and biologics has outpaced regulatory frameworks, necessitating innovative approaches to postmarketing surveillance.<sup>[5]</sup> As frontline healthcare providers, pharmacists and pharmacy technicians are uniquely positioned to contribute to pharmacovigilance efforts. Their role in identifying, reporting, and mitigating ADRs has become increasingly significant as the scope of pharmacy practice has shifted from a product-oriented to a patient-centered approach.<sup>[6]</sup> Despite this, studies have consistently highlighted gaps in knowledge, attitudes, and practices (KAPs) related to pharmacovigilance among pharmacists, particularly in developing regions, including KSA.<sup>[7,8]</sup>

Globally, the underreporting of ADRs remains a major obstacle to effective pharmacovigilance. Studies indicate that <10% of all ADRs are reported due to a lack of awareness, time constraints, and misconceptions about the reporting process.<sup>[9]</sup> Pharmacovigilance systems vary widely across countries, reflecting differences in healthcare infrastructure, regulatory frameworks, and professional practices. High-income countries such as Europe and North America have well-established pharmacovigilance systems supported by mandatory reporting requirements and advanced technologies such as electronic health records. In contrast, low- and middle-income countries face significant challenges,

including limited resources, inadequate training, and cultural barriers to reporting.<sup>[10]</sup> For example, a study in Pakistan found that only 43% of healthcare professionals correctly identified the definition of pharmacovigilance, and <20% had ever reported an ADR.<sup>[11]</sup> Similarly, in India, Mahendra *et al.* reported that while pharmacists had a positive attitude toward ADR reporting, their knowledge and practices were suboptimal due to insufficient training and awareness.<sup>[12]</sup>

In the Middle East, pharmacovigilance is still in its developmental stages. A study in Kuwait by Alsaleh *et al.* highlighted that although pharmacists recognized the importance of ADR reporting, systemic barriers such as lack of time and unclear reporting procedures hindered their participation.<sup>[13]</sup> In the United Arab Emirates, Shanableh *et al.* found that while most pharmacists were willing to report ADRs, they lacked the necessary training and resources to do so effectively.<sup>[10]</sup> These findings underscore the need for targeted interventions to strengthen pharmacovigilance systems in the region.

In KSA, the National Pharmacovigilance and Drug Safety Center (NPC) was established to address these challenges and promote ADR reporting. However, the success of such initiatives depends on the active participation of healthcare professionals, particularly pharmacists and pharmacy technicians. Previous studies in KSA have shown mixed findings regarding the KAP of pharmacists toward pharmacovigilance. For example, a survey by Alshammari *et al.* reported that while most pharmacists recognized the importance of ADR reporting, only a minority knew the official reporting mechanisms.<sup>[4]</sup> Similarly, Faqih and Fageehi found that <22% of pharmacists in their study had ever reported an ADR despite acknowledging its importance.<sup>[7]</sup> Pharmacovigilance has gained increasing attention in recent years in KSA, driven by initiatives from the Saudi Food and Drug Authority and the NPC. Despite these efforts, studies suggest that the pharmacovigilance system is underutilized. For instance, Almandil reported that only 36.9% of healthcare professionals in KSA were aware of the NPC, and less than half knew how to report ADRs.<sup>[14]</sup> The role of pharmacists in pharmacovigilance is particularly critical in KSA, where the healthcare system relies heavily on expatriate professionals. A study by Abdulsalim *et al.* in Qassim revealed that while 93% of pharmacists believed ADR reporting was necessary, only 21.9% had ever reported an ADR.<sup>[8]</sup> This gap between knowledge and practice highlights the need for targeted training programs and awareness campaigns. Moreover, the inclusion of pharmacovigilance in pharmacy curricula has been

suggested as a long-term strategy to improve the practice of pharmacovigilance in these studies.

The literature review reveals significant inconsistencies in the assessment of KAP related to pharmacovigilance among pharmacists in KSA. Most studies have focused on the KAP by pharmacists, with little attention given to the involvement of pharmacy technicians. This study aims to address this gap by providing a comprehensive assessment of the KAP of pharmacists and pharmacy technicians toward pharmacovigilance and ADR reporting. Given the increasing global emphasis on patient safety and medication error prevention, this study aligns with current international priorities by addressing critical gaps in ADR reporting practices among pharmacy professionals. The findings are expected to inform policy and practice, contributing to developing more effective pharmacovigilance systems in KSA and internationally.

## METHODS

This study utilized a descriptive cross-sectional design to evaluate the KAP of pharmacists and pharmacy technicians regarding pharmacovigilance and ADR reporting. It was conducted at the Armed Forces Hospital in the Southern Region (AFHSR) of Saudi Arabia, a tertiary care facility serving a diverse population, including military personnel and civilians. The research lasted from October 2023 to January 2024.

The target population comprised pharmacists and pharmacy technicians employed at the AFHSR. These healthcare professionals were selected due to their critical role in identifying and reporting ADRs and their direct involvement in patient care and medication safety.

The inclusion criteria were pharmacists and pharmacy technicians currently employed at the AFHSR and participants who provided informed consent to participate in the study.

Exclusion criteria included healthcare professionals other than pharmacists, pharmacy technicians, and participants who declined to provide informed consent.

The sample size was calculated using the Raosoft online sample size calculator<sup>[15]</sup> based on the total population of 225 pharmacists and pharmacy technicians at the AFHSR (123 pharmacists and 102 pharmacy technicians). With a confidence level of 95%, a margin of error of 5%, and an anticipated response rate of 50%, the minimum required sample size was estimated to be 175 participants. The study aimed to recruit all eligible participants to account for potential nonresponses.

A convenience sampling method was employed to recruit participants due to practical constraints; however, efforts were made to ensure wide representation by inviting all eligible pharmacists and pharmacy technicians at the facility. All pharmacists and pharmacy technicians working at the AFHSR were invited to participate in the study through E-mail and WhatsApp groups. This approach ensured that the survey link reached the maximum number of eligible participants within the study period.

Data were collected using a structured, self-administered online questionnaire adapted from a validated instrument previously used in a similar study conducted in Libya.<sup>[16]</sup> The original questionnaire was modified to align with Saudi Arabia's context and this study's objectives. A panel of experts in pharmacovigilance and healthcare research reviewed the final version of the questionnaire to ensure its validity and relevance.

The questionnaire consisted of four sections:

1. Sociodemographic data: This section collected participants' ages, genders, nationalities, qualifications, and years of professional experience
2. Knowledge about pharmacovigilance: This section assessed participants' understanding of pharmacovigilance concepts, including ADR reporting processes, definitions, and the role of pharmacists and pharmacy technicians in pharmacovigilance
3. Attitudes toward pharmacovigilance: This section evaluated participants' perceptions and opinions about the importance of pharmacovigilance, its inclusion in pharmacy curricula, and the necessity of compulsory ADR reporting
4. Practices related to pharmacovigilance: This section captured participants' self-reported ADR identification and reporting practices and their preferred methods of reporting ADRs.

The questionnaire underwent rigorous expert validation and pilot testing to ensure clarity and relevance. The questionnaire was distributed electronically using the Google Forms. Participants received the survey link through E-mail and WhatsApp groups, ensuring accessibility and convenience. The survey introduction included a brief explanation of the study objectives, the voluntary nature of participation, and assurances of confidentiality. Participants were required to provide informed consent before proceeding to the survey questions. The data collection period spanned 4 weeks in January 2024.

The research Ethics Committees at King Khalid University (HAPO-06-B-001) and the Research Ethics Committee of AFHSR (ECM# 2024-116) approved the

study, adhering to the ethical principles outlined in the Declaration of Helsinki. Participants were informed that participation was voluntary and that they could withdraw from the study without providing a reason. To ensure confidentiality, no personally identifiable information was collected. The data were anonymized and stored securely, accessible only to the research team.

The collected data were exported from Google Forms into Microsoft Excel and analyzed using the Statistical Package for the Social Sciences (SPSS) software, version 28.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics, including frequencies and percentages, were used to summarize the categorical variables such as age, gender, qualifications, and responses to knowledge, attitude, and practice items.

Inferential statistics were used to identify the associations between participants' sociodemographic characteristics and their KAPs regarding pharmacovigilance. The Chi-square test was used to assess the statistical significance of these associations.  $P <0.05$  was considered statistically significant. To ensure the validity of the analysis, missing data were handled using pairwise deletion.

The primary outcome variables were as follows:

1. Knowledge: Assessed based on participants' responses to questions about pharmacovigilance definitions, ADR reporting processes, and the role of pharmacists and pharmacy technicians in pharmacovigilance
2. Attitudes: This was evaluated based on participants' agreement with statements about the importance of pharmacovigilance, the need for its inclusion in pharmacy curricula, and the necessity of compulsory ADR reporting
3. Practices: Examined based on participants' self-reported experiences with ADR identification and reporting and their preferred methods of reporting ADRs.

The independent variables included participants' age, gender, qualifications, nationality, and years of professional experience.

The reliability of the questionnaire was assessed using Cronbach's alpha, with a threshold of  $\geq 0.7$  considered acceptable for internal consistency. Content validity was ensured through expert review and pilot testing of the questionnaire with a small sample of pharmacists and pharmacy technicians ( $n = 10$ ) who were not part of the main study. Feedback from the pilot testing was used to refine the questionnaire for clarity and relevance.

**Table 1: Sociodemographic characteristics of participants**

Personal characteristics	n (%)
Age groups (years)	
20–25	21 (10.5)
26–30	51 (25.5)
31–35	57 (28.5)
36–40	37 (18.5)
41–45	19 (9.5)
>45	15 (7.5)
Gender	
Male	137 (68.5)
Female	63 (31.5)
Qualification	
B Pharm	79 (39.5)
Diploma	59 (29.5)
Master	15 (7.5)
Pharm D	43 (21.5)
PhD	4 (2.0)
Nationality	
Saudi	165 (82.5)
Non-Saudi	35 (17.5)
Egyptian	12 (6.0)
Jordanian	4 (2.0)
Sudanese	3 (1.5)
Filippino	13 (6.5)
Indian	3 (1.5)
Experience since graduation (years)	
<5	69 (34.5)
5–10	54 (27.0)
11–15	38 (19.0)
16–20	19 (9.5)
21–25	11 (5.5)
>30	9 (4.5)

## RESULTS

Two hundred participants completed the survey, achieving a response rate of approximately 88.9%. Table 1 provides a summary of participants' sociodemographic characteristics. Most participants were male (68.5%), while females accounted for 31.5% of the sample. Most participants were aged between 31–35 years (28.5%) and 26–30 years (25.5%), with only 7.5% aged over 45 years. Regarding educational qualifications, 39.5% held a Bachelor of Pharmacy (BPharm) degree, 21.5% had a Doctor of Pharmacy (PharmD) degree, and 29.5% held a Diploma. Only 2% of participants were PhD-qualified. Most respondents (82.5%) were Saudi nationals, and 33% had less than 5 years of professional experience, while 27% had 5–10 years of experience. Overall, comparative analyses between pharmacists and pharmacy technicians revealed no statistically significant differences in knowledge, attitudes, practices, or perceived barriers related to pharmacovigilance and

ADR reporting ( $P > 0.05$  for all comparisons). Both professional groups demonstrated similar levels of awareness, positive attitudes, reporting practices, and perceptions of barriers. Therefore, the following results present the combined data analysis of both groups.

Participants demonstrated a generally high level of knowledge about pharmacovigilance [Table 2]. A majority (87%) indicated the awareness of the concept of pharmacovigilance, and 91% were familiar with ADRs. More than half (52.5%) correctly identified the best definition of pharmacovigilance, while 84.5% knew that all severe ADRs should be reported. In addition, 83.5% of participants were aware of a pharmacovigilance center in Saudi Arabia, and 71% knew the appropriate procedures for ADR reporting. Furthermore, 91.5% recognized that pharmacists and pharmacy technicians

are responsible for reporting ADRs, and 95.5% agreed that pharmacists serve as the first point of contact for ADR reporting.

Participants' knowledge about pharmacovigilance varied significantly by age, gender, and educational qualifications [Table 3]. Those over 45 years were the most knowledgeable ( $P = 0.035$ ), and females exhibited significantly higher knowledge levels than males ( $P = 0.019$ ). Participants with Master's or PhD qualifications were also considerably more knowledgeable than those with lower qualifications ( $P = 0.010$ ). However, no significant differences in knowledge were observed based on nationality or years of professional experience.

The majority of participants demonstrated positive attitudes toward pharmacovigilance [Table 4]. Nearly

**Table 2: Participants' knowledge of pharmacovigilance and adverse drug reaction reporting**

Knowledge items	n (%)
Which best defines pharmacovigilance?	
Don't know	9 (4.5)
The science and activities of detecting, assessing, understanding and preventing adverse effects	105 (52.5)
The science of detecting the type and incidence of ADRs after a drug is marketed	54 (27.0)
The science of monitoring ADRs happening in a hospital	32 (16.0)
Do you know about ADRs?	
No	18 (9.0)
Yes	182 (91.0)
Which ADRs should be reported?	
ADRs to herbal and nonallopathic drugs	8 (4.0)
ADRs to new drugs	12 (6.0)
All serious ADRs	169 (84.5)
Unknown ADRs to old drugs	11 (5.5)
Do you know that there is a center of pharmacovigilance in Saudi Arabia?	
No	33 (16.5)
Yes	167 (83.5)
Do you know how to report adverse drug reactions to the relevant authorities in Saudi Arabia?	
No	58 (29.0)
Yes	142 (71.0)
Do you know that pharmacists and pharmacy technicians are responsible for reporting adverse drug reactions?	
No	17 (8.5)
Yes	183 (91.5)
Are pharmacists the first point of contact for people to report ADRs?	
No	9 (4.5)
Yes	191 (95.5)
Should patients be advised about ADRs every time their medications are dispensed?	
No	30 (15.0)
Yes	170 (85.0)
Should female patients be asked if they are pregnant when dispensing medications to them?	
No	4 (2.0)
Yes	196 (98.0)
Should pharmacy students be taught how to report ADRs?	
No	6 (3.0)
Yes	194 (97.0)

ADRs=Adverse drug reactions

all respondents (94%) agreed that reporting ADRs is an essential role of pharmacists, and 90% supported the inclusion of pharmacovigilance in pharmacy curricula. In addition, 77.5% of participants believed that ADR reporting should be made compulsory, and 91.5% expressed a willingness to practice pharmacovigilance if they received appropriate training. Most participants (85%) agreed that patients should be advised about ADRs whenever medications are dispensed, and 98% stated that female patients should be asked about pregnancy status before dispensing medications.

Participants' self-reported practices regarding pharmacovigilance and ADR reporting were generally

encouraging [Table 5]. Approximately 79.5% expressed a willingness to implement ADR reporting in their practice, and 71% reported having identified ADRs in patients. However, only 47.5% had reported ADRs, highlighting a gap between knowledge and practice; among those who reported ADRs, 61% preferred using websites to submit ADR information to the relevant authorities, while others preferred E-mail or direct contact.

Despite the positive attitudes and willingness to engage in pharmacovigilance, several barriers to ADR reporting were identified. Participants cited a lack of time (65%), insufficient training (58%), and uncertainty about reporting procedures (49%) as the primary obstacles.

## DISCUSSION

This study aimed to assess the KAP of pharmacists and pharmacy technicians toward pharmacovigilance ADR reporting at a tertiary care facility in Saudi Arabia. Unlike previous studies in Saudi Arabia, this research uniquely includes pharmacy technicians alongside pharmacists, providing a comprehensive perspective on pharmacovigilance practices within healthcare teams. The findings provide valuable insights into pharmacovigilance awareness and engagement among healthcare professionals in the region. The absence of significant differences between pharmacists and pharmacy technicians across knowledge, attitudes, practices, and barriers suggests uniform exposure to institutional training, policies, and work environments. In addition, collaborative practice models and shared responsibilities within pharmacy departments likely contributed to this similarity.

The results revealed a high level of knowledge about pharmacovigilance among participants, with 87% being aware of the concept and 91% being familiar with ADRs. These findings are consistent with previous studies conducted in Saudi Arabia and other countries, which also reported high levels of awareness among pharmacists.<sup>[17]</sup> A study from Libya reported similar levels of knowledge among healthcare professionals.<sup>[16]</sup>

However, while knowledge levels were generally high, gaps were observed in specific areas, such as understanding the precise definition of

Personal characteristics	Does not know, n (%)	Knows, n (%)	P
Age groups (years)			
20–25	7 (33.3)	14 (66.7)	0.035 <sup>†</sup>
26–30	5 (9.8)	46 (90.2)	
31–35	7 (12.3)	50 (87.7)	
36–40	6 (16.2)	31 (83.8)	
41–45	1 (5.3)	18 (94.7)	
>45	0	15 (100.0)	
Gender			
Male	23 (16.8)	114 (83.2)	0.019 <sup>†</sup>
Female	3 (4.8)	60 (95.2)	
Qualification			
BPharm	7 (8.9)	72 (91.1)	0.010 <sup>†</sup>
Diploma	17 (28.8)	42 (71.2)	
Master	0	15 (100.0)	
PharmD	2 (4.7)	41 (95.3)	
PhD	0	4 (100.0)	
Nationality			
Saudi	24 (14.5)	141 (85.5)	0.158
Non-Saudi	2 (5.7)	33 (94.3)	
Experience since graduation (years)			
<5	9 (13.0)	60 (87.0)	0.618
5–10	8 (14.8)	46 (85.2)	
11–15	6 (15.8)	32 (84.2)	
16–20	3 (15.8)	16 (84.2)	
21–25	0	11 (100.0)	
>30	0	9 (100.0)	

<sup>†</sup>Statistically significant

Table 4: Participants' attitudes toward pharmacovigilance and adverse drug reaction reporting

Attitude items	Disagree, n (%)	Neutral, n (%)	Agree, n (%)
Reporting ADRs is an essential role of the pharmacist	1 (0.5)	11 (5.5)	188 (94.0)
Pharmacovigilance needs to be included in the pharmacy curricula	6 (3.0)	14 (7.0)	180 (90.0)
Reporting ADRs must be made compulsory	11 (5.5)	34 (17.0)	155 (77.5)
I would practice pharmacovigilance if I received training	7 (3.5)	10 (5.0)	183 (91.5)

ADRs=Adverse drug reactions

**Table 5: Participants' self-reported practices related to pharmacovigilance and adverse drug reaction reporting**

Practice items	n (%)
I am willing to implement ADRs reporting in my practice	
No	3 (1.5)
Yes if trained	38 (19.0)
Yes totally	159 (79.5)
Have you ever recognized ADRs in any patients?	
No	58 (29.0)
Yes	142 (71.0)
Have you ever reported an ADRs?	
No	105 (52.5)
Yes	95 (47.5)
Which method would you prefer to send ADRs information to an ADR reporting center?	
Websites	122 (61.0)
Direct contact	74 (37.0)
Post	4 (2.0)

ADRs=Adverse drug reactions

pharmacovigilance and the detailed procedures for ADR reporting. This aligns with findings from studies in other regions, highlighting that while pharmacists are generally aware of pharmacovigilance, their understanding of its operational aspects is often limited.<sup>[18-21]</sup> Such gaps may hinder the effective implementation of ADR reporting systems.

Knowledge levels were significantly associated with age, gender, and educational qualifications. Participants aged over 45 years and those with higher academic qualifications demonstrated more excellent knowledge, which may reflect their more extended professional experience and advanced training. Similar trends have been observed in studies conducted in Malaysia and Nigeria, where senior pharmacists with postgraduate qualifications exhibited higher knowledge levels than their junior counterparts.<sup>[21,22]</sup> The findings also align with a study by Palaian *et al.*, which emphasized the role of continuous education in improving pharmacovigilance knowledge among healthcare professionals.<sup>[19]</sup>

The study participants exhibited overwhelmingly positive attitudes toward pharmacovigilance, with 94% agreeing that ADR reporting is an essential role of pharmacists and 90% supporting its inclusion in pharmacy curricula. These findings are consistent with studies conducted in other countries where healthcare professionals strongly support pharmacovigilance initiatives.<sup>[23,24]</sup>

The willingness of 91.5% of participants to engage in pharmacovigilance if provided with appropriate training underscores the importance of continuous professional development programs. This finding aligns with the work of Elkalmi *et al.*, who emphasized the role of targeted training programs in improving pharmacists' attitudes

and engagement with pharmacovigilance.<sup>[18]</sup> Similarly, a study in Ethiopia by Hailu and Mohammed found that training interventions significantly enhanced healthcare professionals' willingness to report ADRs.<sup>[20]</sup> The strong support for making ADR reporting compulsory (77.5%) further highlights the participants' recognition of its importance in ensuring medication safety. However, the gap between positive attitudes and actual practices, as discussed below, indicates that structural barriers may limit the translation of these attitudes into action.

Despite high levels of knowledge and positive attitudes, the study revealed a significant gap in the actual practice of ADR reporting. While 71% of participants reported identifying ADRs in their practice, only 47.5% had ever reported them. This finding is consistent with global trends, as the underreporting of ADRs remains a persistent challenge in pharmacovigilance systems worldwide. Studies in other countries have similarly reported that <50% of pharmacists actively report ADRs despite high levels of awareness.<sup>[25,26]</sup>

The primary barriers to ADR reporting identified in this study, including lack of time, insufficient training, and uncertainty about reporting procedures, have been widely documented in the literature. For example, a survey by Lopez-Gonzalez *et al.* highlighted that underreporting is often attributed to a lack of knowledge about reporting ADRs and the perception that reporting is time-consuming.<sup>[27]</sup> Similarly, another study found that a lack of motivation and unclear reporting guidelines were the significant barriers to ADR reporting.<sup>[26]</sup> These barriers underscore the need for simplified reporting processes and comprehensive training programs to empower healthcare professionals to participate actively in pharmacovigilance. The barrier related to insufficient training aligns with recent studies emphasizing the critical role of continuous professional development and targeted training workshops in improving ADR reporting rates among healthcare professionals.<sup>[28,29]</sup> Similarly, perceived time constraints could be effectively addressed by implementing simplified electronic reporting systems, as recent international pharmacovigilance initiatives demonstrated.<sup>[30,31]</sup>

The findings of this study are broadly consistent with those of previous studies conducted in Saudi Arabia, but some notable differences were observed. For instance, while this study found high levels of knowledge and positive attitudes, a survey by Mahmoud *et al.* reported lower levels of awareness among pharmacy students in Saudi Arabia, highlighting the need for greater emphasis on pharmacovigilance education during undergraduate training.<sup>[32]</sup> In addition, while the current study identified lack of time as a significant barrier, other regional

studies have highlighted cultural factors, such as fear of legal consequences or blame, as substantial deterrents to ADR reporting.<sup>[14]</sup>

Globally, the findings align with studies conducted in high-income and low-income countries, which have consistently reported gaps between KAPs related to pharmacovigilance. For example, a systematic review by Varallo *et al.* found that while pharmacists worldwide generally recognize the importance of pharmacovigilance, actual reporting rates remain low due to similar barriers.<sup>[26]</sup> Furthermore, a study by Adedeji *et al.* in Nigeria emphasized that integrating pharmacovigilance into routine clinical workflows could improve ADR reporting rates.<sup>[25]</sup>

The findings of this study have important implications for improving pharmacovigilance systems in Saudi Arabia. First, the high levels of knowledge and positive attitudes among pharmacists and pharmacy technicians suggest they are well-positioned to play a central role in pharmacovigilance initiatives. However, the gap between knowledge and practice highlights the need for targeted interventions to address the identified barriers.

Training programs should enhance pharmacists' understanding of ADR reporting procedures and provide practical guidance on navigating reporting systems. Additionally, simplifying the reporting process through user-friendly electronic platforms and mobile applications could help reduce the time burden associated with ADR reporting. Policymakers should also consider introducing mandatory ADR reporting requirements, as supported by most participants in this study. Moreover, integrating pharmacovigilance education into undergraduate pharmacy curricula could help address knowledge gaps earlier, as Almandil recommended.<sup>[14]</sup> Policymakers and healthcare administrators are advised to mandate ADR reporting and integrate user-friendly, time-efficient online ADR reporting platforms into routine pharmacy workflows. Furthermore, educational institutions should incorporate practical pharmacovigilance training into undergraduate and postgraduate pharmacy curricula to bridge the gap between theoretical knowledge and actual practice.

This study has several limitations that should be acknowledged. First, convenience sampling may have introduced selection bias, as participants more interested in pharmacovigilance may have been more likely to respond to the survey. Convenience sampling may limit generalizability; thus, future studies should employ randomized sampling methods. Second, the reliance on self-reported data may have led to social desirability bias, with participants potentially overstating their

knowledge, attitudes, or practices. Finally, the study was conducted at a single tertiary care facility, which may limit the generalizability of the findings to other healthcare settings in Saudi Arabia.

Future studies should consider using randomized sampling methods to enhance the generalizability of findings. Additionally, qualitative research could provide deeper insights into the barriers and facilitators of ADR reporting from the perspective of healthcare professionals. Longitudinal studies are also needed to evaluate the impact of training programs and policy interventions on pharmacovigilance practices over time.

This study highlights the high levels of knowledge and positive attitudes toward pharmacovigilance among pharmacists and pharmacy technicians in Saudi Arabia, alongside a significant gap in actual ADR reporting practices. While participants demonstrated a strong willingness to engage in pharmacovigilance, structural barriers, such as lack of time, insufficient training, and unclear reporting procedures, hinder their active participation. Addressing these barriers through targeted training programs, simplified reporting systems, and mandatory reporting policies could significantly enhance the effectiveness of pharmacovigilance systems. Furthermore, integrating pharmacovigilance education into undergraduate pharmacy curricula and continuous professional development programs could ensure sustained improvements in ADR reporting practices. These measures are essential for promoting medication safety and protecting public health in Saudi Arabia and beyond.

## AUTHORS' CONTRIBUTION

SA conceived and designed the study. All authors contributed to designing of data collection tool, data collection and analysis. MA drafted the manuscript. All authors reviewed and approved the final draft of the manuscript.

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## Conflicts of interest

There are no conflicts of interest.

## REFERENCES

- World Health Organization (WHO). Pharmacovigilance: Ensuring the Safe use of Medicines. Geneva: WHO; 2024.
- Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: A meta-analysis of prospective studies. JAMA 1998;279:1200-5.

3. Wiffen P. Adverse Drug Reactions In Hospital Patients A Systematic Review Of The Prospective and Retrospective Studies. Oxford: Bandolier; 2002.
4. Alshammari TM, Alamri KK, Ghawa YA, Alohalil NF, Abualkhol SA, Aljadhey HS. Knowledge and attitude of health-care professionals in hospitals towards pharmacovigilance in Saudi Arabia. *Int J Clin Pharm* 2015;37:1104-10.
5. Khan MA, Hamid S, Babar ZU. Pharmacovigilance in high-income countries: Current developments and a review of literature. *Pharmacy (Basel)* 2023;11:10.
6. Kasliwal R. Spontaneous reporting in pharmacovigilance: Strengths, weaknesses and recent methods of analysis. *J Clin Prev Cardiol* 2012;1:20-3.
7. Faqih MA, Fageehi WA. Pharmacist's knowledge, attitude, and practice towards pharmacovigilance and adverse drug reactions reporting process: A cross-sectional survey. *Int J Med Dev Ctries* 2019;33:9-4.
8. Abdulsalim S, Farooqui M, Alshammari MS, Alotaibi M, Alhazmi A, Alqasomi A, et al. Evaluation of knowledge, attitudes, and practices about pharmacovigilance among community pharmacists in Qassim, Saudi Arabia. *Int J Environ Res Public Health* 2023;20:3548.
9. Shamim S, Sharib SM, Malhi SM, Muntaha SU, Raza H, Ata S, et al. Adverse drug reactions (ADRS) reporting: Awareness and reasons of under-reporting among health care professionals, a challenge for pharmacists. *Springerplus* 2016;5:1778.
10. Shanableh S, Zainal H, Alomar M, Palaian S. A national survey of knowledge, attitude, practice, and barriers towards pharmacovigilance and adverse drug reaction reporting among hospital pharmacy practitioners in the United Arab Emirates. *J Pharm Policy Pract* 2023;16:92.
11. 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;6:29.
12. Mahendra BJ, Sandeep A, Soumya M. A survey on assessing the knowledge, attitude and behavior of community pharmacists to adverse drug reaction-related aspects. *Indian J Pharm Pract* 2012;5:51-5.
13. 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;25:1184-93.
14. Almandil NB. Healthcare professionals' awareness and knowledge of adverse drug reactions and pharmacovigilance. *Saudi Med J* 2016;37:1359-64.
15. Raosoft Sample Size Calculator, 2004. Raosoft. Available from: Available from: <http://www.raosoft.com/samplesize.html>. [Last accessed on 2023 Oct 15].
16. Atia A, Botto A, Alarbi S. Knowledge, attitudes and practices of pharmacists about pharmacovigilance, Libya. *East Mediterr Health J* 2021;27:693-7.
17. Alshayban D, Mahmoud MA, Islam MA, Alshammari S, Alsulaiman D. Pharmacovigilance perception and knowledge among pharmacists and interns in Saudi Arabia. *Risk Manag Healthc Policy* 2020;13:55-61.
18. Elkalmi RM, Hassali MA, Ibrahim MI, Widodo RT, Efan QM, Hadi MA. Pharmacy students' knowledge and perceptions about pharmacovigilance in Malaysian public universities. *Am J Pharm Educ* 2011;75:96.
19. Palaian S, Ibrahim MI, Mishra P. Health professionals' knowledge, attitude and practices towards pharmacovigilance in Nepal. *Pharm Pract (Granada)* 2011;9:228-35.
20. Hailu AD, Mohammed SA. Adverse drug reaction reporting in Ethiopia: Systematic review. *Biomed Res Int* 2020;2020:8569314.
21. Aziz Z, Siang TC, Badarudin NS. Reporting of adverse drug reactions: Predictors of under-reporting in Malaysia. *Pharmacoepidemiol Drug Saf* 2007;16:223-8.
22. Oshikoya KA, Awobusuyi JO. Perceptions of doctors to adverse drug reaction reporting in a teaching hospital in Lagos, Nigeria. *BMC Clin Pharmacol* 2009;9:14.
23. van Grootenhuis AC, van Puijenbroek EP, de Jong-van den Berg LT. Contribution of pharmacists to the reporting of adverse drug reactions. *Pharmacoepidemiol Drug Saf* 2002;11:205-10.
24. Qassim S, Metwaly Z, Shamsain M, Al Hariri Y. Reporting adverse drug reactions: Evaluation of knowledge, attitude and practice among community pharmacists in UAE. *IOSR J Pharm* 2014;22:31-40.
25. Adedeji WA, Adegoke AB, Fehintola FA. Adverse drug reactions reporting practice and associated factors among community health extension workers in public health facilities, Southwest, Nigeria. *Pan Afr Med J* 2021;40:165.
26. Varallo FR, Guimarães Sde O, Abjaude SA, Mastrianni Pde C. Causes for the underreporting of adverse drug events by health professionals: A systematic review. *Rev Esc Enferm USP* 2014;48:739-47.
27. Lopez-Gonzalez E, Herdeiro MT, Figueiras A. Determinants of under-reporting of adverse drug reactions: A systematic review. *Drug Saf* 2009;32:19-31.
28. Putri RA, Ikawati Z, Rahmawati F, Yasin NM. An awareness of pharmacovigilance among healthcare professionals due to an underreporting of adverse drug reactions issue: A systematic review of the current State, Obstacles, and Strategy. *Curr Drug Saf* 2024;19:317-31.
29. Cervantes-Arellano MJ, Castelán-Martínez OD, Marín-Campos Y, Chávez-Pacheco JL, Morales-Ríos O, Ubaldo-Reyes LM. Educational interventions in pharmacovigilance to improve the knowledge, attitude and the report of adverse drug reactions in healthcare professionals: Systematic review and meta-analysis. *Daru* 2024;32:421-34.
30. Shalviri G, Mohebbi N, Mirbaha F, Majdzadeh R, Yazdizadeh B, Gholami K, et al. Improving adverse drug event reporting by healthcare professionals. *Cochrane Database Syst Rev* 2024;10:CD012594.
31. Garashi HY, Steinke DT, Schafheutle EI. A systematic review of pharmacovigilance systems in developing countries using the WHO pharmacovigilance indicators. *Ther Innov Regul Sci* 2022;56:717-43.
32. Mahmoud MA, Alsowaida Y, Alshammari T, Khan TM, Alrasheedy A, Hassali MA, et al. Community pharmacists' knowledge, behaviors and experiences about adverse drug reaction reporting in Saudi Arabia. *Saudi Pharm J* 2014;22:411-8.