Journal of Pioneering Medical Sciences
Received: August 03, 2025 | Accepted: December 22, 2025 | Published: February 05, 2026
Volume 15, Issue 01, Pages 50-57

DOI https://doi.org/10.47310/jpms2026150107

Pharmacists' Knowledge, Attitudes and Practices Toward Adverse Drug Reaction Reporting and Pharmacovigilance in Saudi Arabia: A Cross-Sectional Study

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Abstract **Background:** Pharmacovigilance and Adverse Drug Reaction (ADR) reporting are essential for medication safety and regulatory decision-making. Pharmacists are positioned to contribute to these activities; however, ADR underreporting remains a persistent challenge in many healthcare systems, including Saudi Arabia. **Objective:** This study aimed to assess pharmacists' knowledge, attitudes and self-reported practices regarding ADR reporting and pharmacovigilance in Saudi Arabia and to examine factors associated with reported ADR reporting behavior. **Methods:** A cross-sectional survey was conducted using a structured, self-administered questionnaire distributed electronically. A total of 215 pharmacists working in hospital settings participated, including both general pharmacists and clinical pharmacists. Data were analyzed using descriptive statistics, correlation analysis and binary logistic regression to explore associations between knowledge, attitudes, professional characteristics and reported ADR reporting practice. **Results:** Most participants demonstrated high awareness of pharmacovigilance concepts (89.8%) and positive attitudes toward ADR reporting (96.3%). In contrast, fewer participants reported adequate ADR reporting practice (32.1%) and less than half indicated familiarity with ADR reporting procedures. Knowledge and attitude scores showed modest but statistically significant positive correlations with reported practice ($p<0.01$). Lower knowledge and attitude scores, professional role, educational level and fewer years of experience were associated with lower likelihood of reported ADR reporting. Commonly reported barriers included uncertainty about reporting procedures, limited access to reporting tools, difficulty confirming ADRs and time constraints. **Conclusion:** Despite high awareness and favorable attitudes toward pharmacovigilance, pharmacists' reported ADR reporting practices remain limited, highlighting a gap between conceptual knowledge and procedural competence. Interventions should prioritize practical, system-integrated training on ADR identification and reporting processes, alongside improved access to reporting mechanisms within routine clinical workflows.

Key Words Pharmacovigilance, Adverse Drug Reactions, ADR Reporting, Pharmacists, Saudi Arabia

INTRODUCTION

Medications are central to modern healthcare delivery; however, their use is frequently associated with Adverse Drug Reactions (ADRs), which contribute substantially to patient harm, increased healthcare utilization and economic burden [1]. Pharmacovigilance and systematic ADR reporting are therefore essential components of medication safety, enabling the detection of safety signals and supporting evidence-based regulatory and clinical decision-making [2,3]. The International Pharmaceutical Federation (FIP) emphasizes that medicine safety monitoring is an integral part of routine clinical practice, underscoring the responsibility of healthcare professionals to contribute to pharmacovigilance activities [4].

Pharmacists, particularly those working in hospital settings, are well positioned to identify suspected ADRs due to their involvement in medication review, monitoring and patient counseling. Clinical pharmacists, in particular, are frequently engaged in therapy optimization, assessment of drug-drug interactions and evaluation of treatment-related

harm, placing them at the interface between prescribing decisions and patient outcomes [5]. Nevertheless, ADR reporting is not limited to clinical pharmacists alone and effective pharmacovigilance systems depend on contributions from pharmacists across different professional roles.

In the Kingdom of Saudi Arabia, pharmacovigilance activities are coordinated by the Saudi Food and Drug Authority (SFDA) through its National Pharmacovigilance Center, which is responsible for receiving ADR reports, issuing safety communications and supporting regulatory oversight [6]. Publicly reported SFDA data indicate a substantial volume of ADR submissions, with approximately 173,000 reports received during the first half of 2024, involving commonly prescribed medications such as amlodipine, atorvastatin, furosemide, metformin and esomeprazole [7]. While these figures suggest increasing engagement with ADR reporting systems, they do not provide insight into the quality of reports, the consistency of reporting across healthcare settings or the extent to which frontline pharmacists contribute to these submissions.

Despite broader healthcare reforms under Saudi Vision 2030, several local studies have documented persistent challenges in ADR reporting, including variability in pharmacists' familiarity with reporting procedures and uncertainty regarding reporting channels [2,8]. National and regional surveys have shown that pharmacists often demonstrate awareness of pharmacovigilance concepts but report limited procedural confidence in submitting ADR reports to the SFDA [9]. Reported barriers include time constraints, lack of clarity regarding reporting processes and perceived complexity of reporting systems [8]. These findings suggest that underreporting may be driven less by attitudinal resistance and more by system-level and practical constraints.

Although previous Saudi studies have explored pharmacists' knowledge, attitudes and practices related to pharmacovigilance, many have focused on community pharmacists or mixed healthcare professional groups, with limited attention to hospital-based practice contexts and role-related differences [2,8,9]. In addition, existing evidence highlights a recurring discrepancy between high self-reported knowledge or positive attitudes and low levels of actual ADR reporting, indicating a gap between conceptual awareness and procedural implementation [3].

Accordingly, this study aims to assess pharmacists' knowledge, attitudes and self-reported practices regarding ADR reporting and pharmacovigilance within hospital settings in Saudi Arabia, while examining professional and experiential factors associated with reporting behavior. By characterizing reported barriers and practice patterns, the study seeks to provide empirical evidence that may inform future system-level and educational efforts aligned with SFDA pharmacovigilance requirements, without extending beyond the descriptive scope of a cross-sectional design.

METHODS

Study Design

A cross-sectional study design was employed to examine pharmacists' knowledge, attitudes and self-reported practices related to Adverse Drug Reaction (ADR) reporting and pharmacovigilance in the Kingdom of Saudi Arabia. Data were collected using a structured online questionnaire distributed through Google Forms during the study period.

Study Participants and Sampling

The study population comprised licensed pharmacists working in hospital settings across Saudi Arabia, including both general pharmacists and clinical pharmacists involved in medication management and patient care. A non-probability convenience sampling approach was used due to the absence of a national sampling frame and the exploratory nature of the study.

Pharmacists were eligible for inclusion if they were licensed to practice in Saudi Arabia, actively working in a hospital environment and involved in clinical or dispensing-related activities. Pharmacists working exclusively in administrative or non-clinical roles were excluded. Participation was voluntary.

Sample size estimation was guided by commonly used parameters for cross-sectional surveys, applying a 95% confidence level and a 5% margin of error based on an estimated pharmacist population. To account for potential incomplete responses, a margin was added, resulting in a final analytical sample of 215 respondents. Given the online distribution method, the response rate could not be precisely determined.

Questionnaire

Data were collected using a self-administered structured questionnaire adapted from previously published and validated instruments assessing pharmacovigilance and ADR reporting among pharmacists and hospital-based practitioners [2,3,8,9]. The questionnaire was reviewed and refined to ensure contextual relevance to hospital pharmacy practice in Saudi Arabia.

The final instrument consisted of four sections:

- Demographic and professional characteristics (age, gender, educational level, years of experience, professional role and practice setting)
- Knowledge related to ADRs and pharmacovigilance
- Attitudes toward ADR reporting and pharmacovigilance
- Self-reported practices related to ADR reporting

Most items in the knowledge, attitude and practice sections used categorical response options (Yes/No/Do not know), consistent with KAP-based survey methodology. Additional questions addressing perceived barriers and facilitators of ADR reporting allowed multiple responses. The questionnaire was administered in English, reflecting the language of pharmacy education and professional practice in Saudi Arabia.

Prior to full deployment, the questionnaire was pilot-tested to assess clarity and internal consistency. Reliability was evaluated using Cronbach's alpha, which demonstrated acceptable internal consistency comparable to similar pharmacovigilance studies conducted in hospital pharmacy settings.

Scoring System

A scoring framework was applied to quantify knowledge, attitudes and self-reported practices related to ADR reporting. Each correct or appropriate response was assigned one point, while incorrect or "do not know" responses were assigned zero. Domain-specific composite scores were calculated by summing item scores.

Knowledge scores ranged from 0 to 10 and were categorized as higher awareness (≥6) or lower awareness (≤5). Attitude scores ranged from 0 to 7 and were categorized as positive (≥4) or less favorable (≤3). Practice scores ranged from 0 to 7 and were categorized as relatively adequate (≥4) or limited (≤3). These thresholds were adopted from previously published KAP-based pharmacovigilance studies among pharmacists and were used to support descriptive and inferential analyses. The scoring system reflects self-reported responses and does not measure actual reporting competence.

Data Analysis

Data were analyzed using the Statistical Package for the Social Sciences (SPSS Inc., Chicago, IL, USA), version 26. Descriptive statistics were used to summarize participant characteristics and response distributions. Categorical variables were presented as frequencies and percentages, while continuous variables were summarized using means and standard deviations.

Associations between pharmacist characteristics and knowledge, attitude and practice scores were explored using chi-square tests. Correlation analysis was conducted to examine relationships among knowledge, attitude and practice scores. Binary logistic regression analysis was performed to identify factors associated with self-reported ADR reporting practice. Statistical significance was set at a p-value of <0.05. No causal inferences were drawn due to the cross-sectional design.

Ethical Considerations

Participants were provided with an information sheet outlining the study objectives, voluntary nature of participation and assurance of anonymity. Electronic informed consent was obtained prior to questionnaire completion and no personally identifiable information was collected.

RESULTS

As shown in Table 1, a total of 215 participants responded to the questionnaire. The majority of respondents were male (61.9%) and the largest age group was 25-29 years (28.8%), followed by 20-24 years (24.7%). Clinical pharmacists accounted for 60.0% of the sample. Most participants held a bachelor's degree (69.7%), while 30.3% had obtained a master's degree. The majority of respondents reported less than 10 years of professional experience (79.5%). With respect to workload indicators, nearly half of the participants spent 5-10 minutes per prescription, with a mean of 23.23±9.24 prescriptions and 46.12±12.69 patients per day.

Table 2 shows the overall levels of knowledge, attitude and practice toward adverse drug reaction reporting among the study participants (n = 215). The majority of respondents demonstrated a good level of knowledge regarding ADR reporting (89.8%), while only 10.2% exhibited poor knowledge. Attitudes toward ADR reporting were predominantly positive, with 96.3% of participants showing

Table 1: Demographic Characteristics of the Study Participants (n = 215)

Variable		N	Percentage
Your gender	Male	133	61.9
	Female	82	38.1
Your age	20-24 years	53	24.7
	25-29 years	62	28.8
	30-34 years	39	18.1
	35-39 years	52	24.2
	More than 40 year	9	4.2
Professional Status	Pharmacist	86	40.0
	Clinical Pharmacist	129	60.0
Highest qualification achieved	Bachelor	150	69.7
	Master's degree	65	30.3
Years of experience	Less than 10 year	171	79.5
	11-20 year	33	15.3
	More than 20 year	11	5.1
Average time per prescription (min)	<5	36	16.7
	5-10	161	47.9
	>10	18	8.4
Prescriptions/day (mean ± SD)	23.23±9.24		
Patients/day (mean ± SD)	46.12±12.69		

Table 2: Overall Levels of Knowledge, Attitude and Practice Toward ADR Reporting (n = 215)

Category		N	Percentage
Knowledge	Good (≥6)	193 (89.8)	89.8
	Poor (≤5)	22 (10.2)	10.2
Attitude	Positive (≥4)	207 (96.3)	96.3
	Negative (≤3)	8 (3.7)	3.7
Practice	Adequate (≥4)	69 (32.1)	32.1
	Inadequate (≤3)	146 (67.9)	67.9

Table 3: Response of the Study Participants to Knowledge-Related Questions (n = 215)

Paragraph		N	Percentage
Aware of the drug side effects reporting program in Saudi Arabia	Yes	159	73.9
	No	14	14.0
	Do not know	12.1	12.1
Necessary to report OTC-related ADRs	Yes	204	94.9
	No	6	2.8
	Do not know	5	2.3
Necessary to report documented ADRs	Yes	176	81.9
	No	26	12.1
	Do not know	13	6.0
Aware of drugs banned due to ADRs	Yes	176	81.9
	No	22	10.2
	Do not know	17	7.9
Heard about pharmacovigilance (PV)	Yes	185	86.0
	No	25	11.6
	Do not know	5	2.4
Know how to report ADR	Yes	95	44.2
	No	60	27.9
	Do not know	60	27.9
Every medicine is safe	Yes	57	26.5
	No	128	59.5
	Do not know	30	14.0
Only severe ADRs should be reported	Yes	61	28.4
	No	139	64.7
	Do not know	15	7.0
Herbal products have no ADRs	Yes	35	16.3
	No	141	65.6
	Do not know	39	18.1
Consulting physicians before reporting ADR is important	Yes	153	71.2
	No	26	12.1
	Do not know	36	16.7

a positive attitude. In contrast, practice levels were less favorable, as only 32.1% of respondents reported adequate practice related to ADR reporting, whereas 67.9% demonstrated inadequate practice.

Table 3 shows participants' responses to knowledge-related questions regarding adverse drug reaction reporting and pharmacovigilance (n = 215). The majority of respondents reported awareness of the drug side effects reporting program in Saudi Arabia (73.9%) and indicated that reporting over-the-counter-related ADRs is necessary (94.9%). Most participants also recognized the necessity of reporting documented ADRs (81.9%) and were aware of drugs that had been banned due to ADRs (81.9%). Awareness of pharmacovigilance concepts was high, with 86.0% reporting that they had heard about pharmacovigilance. However, less than half of the respondents indicated that they knew how to report an ADR (44.2%), while 27.9% reported not knowing how to report and an equal proportion were uncertain. Regarding perceptions of medication safety, 59.5% disagreed with the statement that every medicine is safe and 64.7% indicated that severe ADRs should be reported. In addition, 65.6% of participants disagreed with the statement that herbal products have no ADRs. With respect to reporting practices, 71.2% agreed that consulting physicians before reporting an ADR is important.

Table 4 shows participants' responses to attitude-related questions toward adverse drug reaction reporting (n = 215). Overall, attitudes toward ADR reporting were highly positive, with most respondents agreeing that pharmacists should be involved in ADR reporting (93.0%) and that ADR reporting benefits patients (98.1%). A large proportion of participants indicated that ADR reporting should be mandatory (80.9%) and that it improves patient safety (96.3%). The majority also perceived ADR reporting as part of their professional role (94.9%) and reported the need to confirm an ADR before reporting it (85.1%). In contrast, perceptions regarding time burden were more variable, as 26.5% of respondents considered ADR reporting to be time-consuming, while more than half disagreed with this statement (54.0%).

Table 5 shows participants' responses to practice-related questions regarding adverse drug reaction reporting (n = 215). Less than half of the respondents reported encountering ADRs during the previous year (43.7%), while only 16.3% indicated that they had never reported an ADR. Although most participants reported reading articles related to ADRs (80.9%), fewer than half reported having received training on ADR reporting (26.5%) or having access to an ADR reporting form at their workplace (23.3%). Approximately half of the respondents indicated that they had previously prevented ADRs (52.1%), whereas attendance at ADR or pharmacovigilance workshops was reported by 38.1% of participants.

Table 6 shows the correlation between knowledge, attitude and practice scores related to adverse drug reaction reporting. A statistically significant positive correlation was observed between knowledge and attitude scores ($r = 0.304$, $p<0.0001$). Knowledge scores were also significantly

Table 4: Response of the Study Participants to Attitude-Related Questions (n = 215)

Paragraph		N	Percentage
Pharmacists should be involved in ADR reporting	Yes	200	93.0
	No	5	2.3
	Do not know	10	4.7
ADR reporting benefits patients	Yes	211	98.1
	No	2	0.9
	Do not know	2	0.9
ADR reporting should be mandatory	Yes	174	80.9
	No	18	8.4
	Do not know	23	10.7
ADR reporting improves patient safety	Yes	207	96.3
	No	4	1.9
	Do not know	4	1.9
ADR reporting is time-consuming	Yes	57	26.5
	No	116	54.0
	Do not know	42	19.5
ADR reporting is part of professional role	Yes	204	94.9
	No	4	1.9
	Do not know	7	3.2
Need to confirm ADR before reporting	Yes	183	85.1
	No	11	5.1
	Do not know	21	9.8

Table 5: Response of the Study Participants to Practice-Related Questions (n = 215)

Paragraph		N	Percentage
Encountered ADRs in last year	Yes	94	43.7
	No	108	50.2
	Do not know	13	6.0
Ever reported an ADR	Yes	35	16.3
	No	168	78.1
	Do not know	12	5.6
Read articles on ADRs	Yes	174	80.9
	No	23	10.7
	Do not know	18	8.4
Prevented ADRs	Yes	112	52.1
	No	38	17.7
	Do not know	65	30.2
Trained on ADR reporting	Yes	57	26.5
	No	138	64.2
	Do not know	20	9.3
Workplace provides ADR form	Yes	50	23.3
	No	145	67.4
	Do not know	20	9.3
Attended ADR/PV workshop	Yes	82	38.1
	No	112	52.1
	Do not know	21	9.8

Table 6: Correlation Between Knowledge, Attitude and Practice Scores

Variables	Correlation (r)	p-value
Knowledge vs. Attitude	0.304	<0.0001**
Knowledge vs. Practice	0.269	0.001**
Attitude vs. Practice	0.227	0.004**

correlated with practice scores (r = 0.269, p = 0.001). In addition, a significant positive correlation was found between attitude and practice scores (r = 0.227, p = 0.004).

Table 7 shows the predictors of adverse drug reaction reporting practice among the study participants. Knowledge score was significantly associated with practice, as participants with poor knowledge scores (≤5) showed higher odds of inadequate ADR reporting practice compared with those with good knowledge scores (OR = 8.07, p = 0.0219). Attitude score was also a significant predictor, with lower attitude scores (≤3) associated with inadequate practice (OR = 2.91, p = 0.041). In addition, professional status, educational qualification and years of experience were significantly associated with ADR reporting practice, as clinical pharmacists, bachelor's degree holders and participants with ≤10 years of experience demonstrated higher odds of inadequate practice (p<0.05).

Table 8 shows participants' perceptions, willingness and barriers toward adverse drug reaction reporting. ADRs were most confirmed through patient interviews (80.1%) and the seriousness of the reaction was the main factor encouraging reporting (53.2%). Most respondents indicated that all types of ADRs should be reported (73.1%). The most frequently reported barriers were the unavailability of reporting forms (39.1%) and uncertainty regarding how and where to report ADRs (33.3%).

Table 7: Predictors of ADR Reporting Practice

Variable	Adequate N	Inadequate N	OR (95% CI)	p-value
Knowledge score				
≤5	1	21	8.07 (1.03-62.98)	0.0219*
≥6	68	125	1 (Ref)	
Attitude score				
≤3	3	5	2.91 (1.04-8.13)	0.041*
≥4	66	141	1 (Ref)	
Professional Status				
Pharmacist	61	100	1 (Ref)	
Clinical Pharmacist	8	46	3.31 (1.28-8.54)	0.0102**
Qualification				
Bachelor	47	97	4.82 (1.67-13.86)	0.0035**
Master	22	23	1 (Ref)	
Years of experience				
≤10 years	50	121	2.94 (1.12-7.68)	0.028*
>10 years	19	25	1 (Ref)	

Ref: The reference, *Significance difference ≤0.05, **Significance difference ≤0.01

Table 8: Perception, Willingness, Factors and Barriers Toward ADR Reporting

Category	Variables	N	%
Confirming the occurrence of ADR	Patient interview	172	80.12%
	Referring to physician	91	42.3%
	Referring literature	72	33.3%
Factors encouraging reporting ADR	The seriousness of the ADR	114	53.2%
	Unusualness of the reaction	39	17.9%
	Involvement of a new drug	47	21.8%
	Confidence in the diagnosis of an ADR	34	16.0%
	All of the above	91	42.3%
Nature of ADRs to be reported	Serious or life-threatening	28	12.8%
	Only severe and new	21	9.6%
	Mild-severe	25	11.5%
	All types of ADRs	157	73.1%
Barriers to reporting ADR	Reporting forms are not available	84	39.1%
	Reporting forms are too complicated	25	11.5%
	Reporting is time-consuming	41	19.2%
	Fear of legal liability of the reported ADR	19	9.0%
	Uncertainty of how and where to report	72	33.3%
	Not sure whether it is an ADR	61	28.2%
	Insufficient knowledge about drugs in detecting ADR	44	20.5%
	Believe that all drugs marketed are safe	11	5.12%
	Fear that it may harm the confidence of my patients	39	17.9%
	Forgetfulness	17	7.7%
	All of the above	54	25.0%

DISCUSSION

This study examined pharmacists' knowledge, attitudes and self-reported practices regarding Adverse Drug Reaction (ADR) reporting and pharmacovigilance in Saudi Arabia and identified a consistent pattern that has been reported in similar settings. While respondents demonstrated high awareness of pharmacovigilance concepts and largely positive attitudes toward ADR reporting, reported engagement in actual reporting activities was limited. This discrepancy between conceptual awareness and reported practice has been described in previous Saudi studies and reflects an ongoing challenge in translating professional responsibility into routine reporting behavior [8,9].

The high level of knowledge reported by participants is comparable to findings from earlier studies conducted in Saudi Arabia and the region, which have shown that pharmacists generally recognize the importance of pharmacovigilance and ADR reporting [2,3]. Awareness of the need to report ADRs related to over-the-counter medicines, documented reactions and herbal products suggests that respondents were familiar with the broad scope of medication safety responsibilities. Similar patterns of awareness have been reported among pharmacists in other Middle Eastern and Asian contexts, indicating that formal exposure to pharmacovigilance concepts is relatively well established [10,11].

However, this reported knowledge did not consistently translate into procedural confidence. A substantial proportion of participants indicated uncertainty regarding how to submit ADR reports, highlighting a gap between theoretical understanding and practical competence. This finding aligns with earlier Saudi research identifying limited familiarity with reporting pathways and operational steps as key contributors to underreporting [9,12]. International studies similarly report that pharmacists may understand the importance of pharmacovigilance but remain uncertain when navigating reporting systems, particularly in the absence of clear institutional guidance or feedback mechanisms [13,14].

Attitudes toward ADR reporting in the present study were predominantly positive, with most respondents viewing reporting as beneficial to patient safety and part of professional responsibility. These findings are consistent with prior Saudi studies demonstrating favorable perceptions of pharmacovigilance among pharmacists and other healthcare professionals [3,8]. Nonetheless, positive attitudes alone were insufficient to ensure regular reporting, reinforcing evidence that attitudinal readiness does not necessarily overcome practical or organizational barriers [15].

Reported practice outcomes further illustrated this gap. Only a minority of participants indicated that they had ever submitted an ADR report, despite many reporting encounters with suspected ADRs in daily practice. This pattern has been widely documented in both hospital and community pharmacy settings, where recognition of ADRs does not consistently result in formal reporting [16,17]. Comparable reporting gaps have also been reported in hospital pharmacists in other regions, including China and South Asia, suggesting that underreporting reflects a broader, system-level issue rather than a context-specific phenomenon [11,13].

The observed correlations between knowledge, attitudes and practice scores support the general assumptions of KAP-based frameworks; however, the modest strength of these associations indicates that knowledge and attitudes alone explain only a limited proportion of reporting behavior. This suggests that structural, organizational and workflow-related factors play a significant role in shaping ADR reporting practices. Similar findings have been reported in previous pharmacovigilance studies, emphasizing the need for interventions that extend beyond educational initiatives [12,14].

Regression analysis further indicated that professional role, educational level and years of experience were associated with reported ADR reporting practice. Pharmacists with lower knowledge and attitude scores, those holding bachelor's degrees and those with fewer years of experience were more likely to report limited reporting activity. These findings are consistent with Saudi and international literature suggesting that advanced training, greater clinical exposure and professional maturity may enhance confidence in ADR identification and reporting [2,8,13]. However, the wide confidence intervals observed for some predictors indicate variability and should be interpreted cautiously.

Barriers identified in this study, including uncertainty regarding reporting procedures, limited access to reporting tools and difficulty confirming suspected ADRs, closely mirror those reported in earlier Saudi studies [9,15]. The persistence of these barriers suggests that underreporting is driven primarily by system-level and process-related constraints rather than lack of awareness or motivation. Although electronic reporting systems are available, their integration into routine clinical workflows and pharmacists' familiarity with their use may remain insufficient. Evidence from Saudi hospital settings indicates that simplifying reporting procedures, providing clear operational guidance and embedding reporting tools within daily practice can improve reporting engagement [8,12].

Overall, the findings indicate that pharmacists in Saudi Arabia demonstrate high awareness and favorable attitudes toward pharmacovigilance, yet reported ADR reporting practices remain limited. This gap appears to reflect challenges related to procedural competence, workflow integration and system support rather than deficiencies in professional intent. Addressing these issues will likely require a combination of practice-oriented training, clearer reporting pathways and organizational support that reinforces ADR reporting as a routine component of pharmacy practice rather than an additional administrative task.

CONCLUSIONS

This study demonstrates that pharmacists working in hospital settings in Saudi Arabia generally report high awareness of pharmacovigilance principles and favorable attitudes toward Adverse Drug Reaction (ADR) reporting. However, reported engagement in ADR reporting remains limited, indicating a gap between conceptual understanding and procedural implementation. The findings suggest that barriers to reporting are primarily related to uncertainty about reporting processes, limited integration of reporting tools into routine workflows, challenges in confirming suspected ADRs and time constraints, rather than lack of professional motivation.

These results indicate that efforts to improve ADR reporting should move beyond general awareness-based training and instead emphasize practical, workflow-oriented approaches. Interventions such as hands-on training in reporting procedures, clearer institutional guidance and improved accessibility of reporting systems within clinical environments may better support pharmacists' participation in pharmacovigilance activities. While the study does not evaluate specific interventions, it provides descriptive evidence that may inform future system-level and educational strategies aimed at strengthening medication safety practices.

Limitations

Several limitations should be considered when interpreting the findings of this study. The cross-sectional design precludes causal inference between knowledge, attitudes and reporting behavior. Data were collected using a self-administered questionnaire, which may be subject to recall bias and social desirability bias. The use of convenience sampling limits the representativeness of the sample and may restrict the generalizability of the results to all pharmacists in Saudi Arabia. In addition, ADR reporting practices were assessed based on self-reported responses rather than verified reporting records, which may not accurately reflect actual reporting behavior. The scoring system used to categorize knowledge, attitude and practice reflects awareness and perceptions rather than objective reporting competence.

Acknowledgement

The authors would like to thank all pharmacists who voluntarily participated in this study for their time and valuable contributions. Their cooperation was essential to the completion of this research.

Data Availability Statement

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Statement of Funding

No external funding was received for this study.

Disclosure of Conflict of Interest

The authors declare that they have no known financial or personal relationships that could have influenced the work reported in this manuscript.

REFERENCES

[1] World Health Organization. *Global Patient Safety Action Plan 2021-2030: Towards Eliminating Avoidable Harm in Health Care*. WHO, 2021, http://www.who.int/publications/i/item/9789240032705.

[2] Alshayban, D. *et al.* "Pharmacovigilance Perception and Knowledge Among Pharmacists and Interns in Saudi Arabia." *Risk Management and Healthcare Policy*, vol. 13, 2020, pp. 55-61. https://doi.org/10.2147/RMHP.S241265.

[3] Alshabi, A.M. *et al.* "Knowledge, Attitude and Practice of Hospital Pharmacists towards Pharmacovigilance and Adverse Drug Reaction Reporting in Najran, Saudi Arabia." *Saudi Pharmaceutical Journal*, vol. 30, no. 7, 2022, pp. 1018-1026. https://doi.org/10.1016/j.jsps.2022.04.014.

[4] FIP. *FIP Statement of Policy: The Role of the Pharmacist in Pharmacovigilance*. International Pharmaceutical Federation, 2006, http://www.fip.org/file/1464.

[5] Dal Pan, G.J. "Ongoing Challenges in Pharmacovigilance." *Drug Safety*, vol. 37, no. 1, 2014, pp. 1-8. https://doi.org/10.1007/s40264-013-0123-x.

[6] Saudi Food and Drug Authority. *National Pharmacovigilance Center: Roles and Reporting System*. 2024a, http://www.sfda.gov.sa.

[7] Saudi Food and Drug Authority. *Over 173,000 Reports of Drug Side Effects in the First Half of 2024*. 2024b, http://www.sfda.gov.sa/en/news/1383810.

[8] Khardali, A. "Exploring the Knowledge, Perception, and Practice of Community Pharmacists in Saudi Arabia toward Pharmacovigilance and Adverse Drug Reaction Reporting: A Nationwide Survey." *Scientific Reports*, vol. 14, no. 1, 2024. https://doi.org/10.1038/s41598-024-55664-8.

[9] Alsheikh, M.Y. and M.M. Alasmari. "A National Survey of Community Pharmacists' Viewpoints About Pharmacovigilance and Adverse Drug Reaction Reporting in Saudi Arabia." *Frontiers in Pharmacology*, vol. 13, 2022. https://doi.org/10.3389/fphar.2022.819551.

[10] Jarab, A.S. *et al.* "Adverse-Drug Reaction Reporting by PharmD Students during Hospital Training." *Saudi Pharmaceutical Journal*, vol. 31, no. 7, 2023, pp. 1149-1156. https://doi.org/10.1016/j.jsps.2023.05.012.

[11] Thilini Madhushika, M. *et al.* "Knowledge, Attitudes, and Practices of Adverse Drug Reaction Reporting Among Healthcare Professionals in Sri Lanka: A Cross-Sectional Study." *Hospital Pharmacy*, vol. 59, no. 1, 2024, pp. 102-109. https://doi.org/10.1177/00185787231194988.

[12] Alqahtani, S.S. *et al.* "Healthcare Professionals' Awareness, Attitudes and Practices towards Pharmacovigilance and Spontaneous Adverse Drug Reaction Reporting in Jazan Province, Saudi Arabia: A Survey Study." *Saudi Pharmaceutical Journal*, vol. 31, no. 6, 2023, pp. 979-988. https://doi.org/10.1016/j.jsps.2023.04.021.

[13] Hu, W. *et al.* "Knowledge, Attitude and Practice of Hospital Pharmacists in Central China Towards Adverse Drug Reaction Reporting: A Multicenter Cross-Sectional Study." *Frontiers in Pharmacology*, vol. 13, 2022. https://doi.org/10.3389/fphar.2022.823944.

[14] Balan, S. "Knowledge, Attitude and Practice of Malaysian Healthcare Professionals toward Adverse Drug Reaction Reporting: A Systematic Review." *International Journal of Pharmacy Practice*, vol. 29, no. 4, 2021, pp. 308-320. https://doi.org/10.1093/ijpp/riab030.

[15] Abdulsalim, S. *et al.* "Evaluation of Knowledge, Attitudes, and Practices about Pharmacovigilance among Community Pharmacists in Qassim, Saudi Arabia." *International Journal of Environmental Research and Public Health*, vol. 20, no. 4, 2023. https://doi.org/10.3390/ijerph20043548.

[16] Ali, M.D. *et al.* "Community Pharmacists' Knowledge, Practice and Barriers toward Adverse Drug Reaction Reporting Systems in Saudi Arabia." *Journal of Young Pharmacists*, vol. 12, no. 1, 2020, pp. 81-85. https://doi.org/10.5530/jyp.2020.12.16.

[17] Alwidyan, T. *et al.* "Knowledge, Attitude, and Practice among Community Pharmacists toward Adverse Drug Reaction Reporting and Pharmacovigilance: A Nationwide Survey." *Exploratory Research in Clinical and Social Pharmacy*, vol. 18, 2025. https://doi.org/10.1016/j.rcsop.2025.100578.