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Knowledge, attitude, and practice in pharmacovigilance and adverse drug reaction reporting among community pharmacists in Erbil city

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Abstract

Background and objective: Pharmacovigilance and adverse drug reaction (ADR) reporting are crucial for safeguarding medication safety. Community pharmacists play a vital role in the identification and reporting of ADRs. The objective of this study is to evaluate the knowledge, attitude, and practice of community pharmacists in Erbil city about pharmacovigilance and ADR reporting.

Methods: A cross-sectional study was carried out utilizing a structured, interviewer-administered questionnaire that involved a sample of 350 community pharmacists via convenience sampling method. The questionnaire collected demographic data and the pharmacist's knowledge, attitude, and practice toward pharmacovigilance and ADR reporting. SPSS was used for data entry and analysis.

Results: Among the participants, 47.4% displayed poor knowledge, 46.6% exhibited moderate knowledge, and merely 6% demonstrated a good knowledge. More than half of the participants (54.9%) maintained an overall positive attitude; however, the majority (58.6%) exhibited poor practices. The results indicated a statistically significant association between participants' knowledge and attitude levels, as well as between knowledge and practice levels (P <0.001). However, there was no statistically significant association between participants attitudes and practice levels (P = 0.815).

Conclusion: The study's findings revealed that slightly more than half of pharmacists had adequate fundamental knowledge of pharmacovigilance and ADR reporting and exhibited generally positive attitudes, yet gaps were evident in the practical application of ADR reporting practices. Additional training and education may still be necessary to gain a more profound understanding of the details of pharmacovigilance and enhance pharmacists' engagement with ADR reporting.

Keywords: Pharmacovigilance; Adverse drug reaction reporting; Community pharmacists; Medication Safety.

Introduction

The World Health Organization (WHO) has defined pharmacovigilance as the "science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems".[1]

Pharmacovigilance is essential for the protection of patient safety by consistently monitoring drug safety to establish risk-benefit profiles by evaluating medication effects after-market release because pre-market clinical trials fail to sufficiently address all safety concerns related to the drugs.[2]

Despite rigorous pharmaceutical approval procedures, ADRs remain a significant public health concern.[3] ADR are defined by WHO as "responses to a drug that are noxious and unintended and that occur at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function".[1] The financial

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consequences of ADRs are substantial, sometimes resulting in increased healthcare costs due to additional medical interventions, prolonged hospital stays, and follow-up therapies.[3]

ADR reporting is the basic backbone of pharmacovigilance since it gives critical data for analyzing the safety profile of medications after-market release.[4] Pharmacists, have a significant role in the detection and reporting of ADRs.[5] Nonetheless, several studies have documented the underreporting of ADRs, particularly in developing nations, with only 10% of serious ADRs being reported to global authorities.[4]

Research indicates that pharmacists in several Arab countries, including Iraq, frequently have deficiencies in their comprehension of pharmacovigilance systems and ADR reporting processes.[6-8] This may result from insufficient knowledge and inadequate understanding of the proper methods for identifying and reporting ADRs.[8] Therefore, the objective of this study is to conduct a comprehensive assessment of the knowledge, attitude, and practice of community pharmacists in Erbil city regarding pharmacovigilance and ADR reporting.

Methods

Study design: A cross-sectional study was carried out among community pharmacists working in different geographic areas of Erbil city. The study was carried out over three months, data collection was conducted between November 1, 2024, to January 30, 2025. The inclusion criteria included licensed community pharmacists who were actively practicing. The exclusion criteria excluded pharmacy assistants, pharmacy students, nurses, pharmacists employed in non-community settings, academic fields, pharmaceutical companies, regulatory bodies, or as medical representatives. The sample size was determined utilizing Epi Info version 7, predicated on a total population of 1,819 pharmacists in Erbil city. A 50% expected frequency, a 95% confidence interval, and a 5% margin of error were utilized to ascertain the sample size. Despite the predicted sample size of 317, we chose to augment it to 350 to accommodate probable non-response rates.

Survey development: A structured questionnaire was designed based on existing literature and prior surveys on pharmacovigilance and ADR reporting, with adaptations made to align with the specific context of Erbil city. The questionnaire included sections on pharmacists' demographics, knowledge, attitude, and practices. The demographic section consisted of 11 items pertaining to background information, including age, gender, level of education, and type of workplace, etc. Knowledge sections composed of 14 questions, which were designed to encompass both general questions to assess overall familiarity and specialized questions to assess their depth of knowledge in certain areas of expertise. A skip logic mechanism was included in particular questions to protect the integrity responses so that the data accurately reflected participants' knowledge instead of random choices. Each familiarity response for general questions and correct answers for specific questions received 'one' score, while non-familiarity responses, wrong answers, and skip logic responses received 'zero' score. Each participant scored 0-14.

The knowledge was categorized as poor (0-4 correct answers), medium (5-9 correct answers), and good (10-14 correct answers). Attitude section was composed of 13 items, which were evaluated on a 5-point Likert scale with a range of "Strongly Disagree" (1) to "Strongly Agree" (5). Negatively worded questions were reversed for their scores before analysis. Participant ratings varied from 13 to 65. The median (50) of the total score classified individuals' attitudes as positive or negative. A total score of 50 and higher is considered a positive attitude, while a score of less than 50 is considered

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a negative attitude. The practice section is composed of 10 items that were presented on a Likert scale ranging from "Never" (1) to "Always" (5). The total scores for each participant ranged from 10 to 35, The practice was categorized as poor (10–18), medium (19–27), and good (28–35).

Pilot study: A pilot study with 15 community pharmacists was conducted, and the results from this pilot study were omitted from the original research. Subsequent to the completion of the pilot study, the questionnaire was enhanced for final use.

Validity and reliability: The expert panel evaluated the questions for comprehensiveness, clarity, and relevance in order to determine the questionnaire's face and content validity. The Cronbach's alpha coefficients were calculated in the sample of 350 participants to assess the reliability of the knowledge, attitude, and practice domains. The internal consistency of the combined three sections, which contained 37 items, was 0.788, indicating acceptable internal consistency.

Data collection: Data were collected mostly through an interviewer-administered questionnaire via a convenience sampling method. However, this approach could not be utilized for all participants due to their busy schedules. Therefore, for a limited number of participants, an online questionnaire was utilized, allowing them to complete it at their convenience prior to the study's conclusion. Overall, out of 350 participants, 60(17%) answered an online questionnaire.

Statistical data analysis: The Statistical Package for Social Sciences (SPSS, version 27) was utilized to code, enter, and analyze the data. Descriptive statistics were employed to describe the demographic data and the participants' knowledge, attitude, and practice. An inferential statistical test, namely Chi-square, was utilized to evaluate associations between variables. *P* value of <0.05 was considered as statistically significant.

Ethical consideration: The study received ethical approval from the Hawler Medical University College of Pharmacy's ethical review committee. Informed permission and confidentiality were communicated orally to each participant prior to their involvement. In addition, all the responses were kept confidential.

Results

Out of total 350 community pharmacists, 36.6% were males and 63.4% were females with the mean (SD) age of 27.69 (4.65) years. More than half (55.1%) of participants were single. The vast majority (95.1%) of participants possessed a bachelor's degree, and 93.4% of participants received their degree in Iraq. Most participants (64.3%) possessed 1-5 years of experience, and the predominant representation was from independent pharmacies at 53.7%. Table 1 presents a comprehensive illustration of the demographic characteristics of the study participants.

Regarding the knowledge level, 47.4% of participants had poor knowledge about pharmacovigilance and ADR reporting, while 46.6% had medium knowledge and only 6% had good knowledge. About half of pharmacists were very familiar/familiar with the term pharmacovigilance; however, 21.4% have never heard of the term, and only 22.3% of pharmacists correctly defined the term. About 90% of pharmacists have complete understanding/ basic understanding of the term ADR. However, only 55.4% were able to correctly define it. Moreover, only 18.9% of the respondents were cognizant of the national pharmacovigilance program in Iraq, and merely 12.3 % were familiar with the local pharmacovigilance program in Erbil. A detailed overview of participants' knowledge is provided in Table 2.

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Table 1 Sample distribution by demographic characteristics (n=350)

Demographic data		No.	(%)
Age (years) [Mean (SD)]		27.69 (4.65)	
Gender	Male	128	(36.6)
	Female	222	(63.4)
Marital status	Single	193	(55.1)
	Married	157	(44.9)
Educational qualification	Bachelor's Degree (B.Sc)	333	(95.1)
	Postgraduate (M.Sc/PhD)	17	(4.9)
Country of graduation	Iraq	327	(93.4)
	Outside Iraq	23	(6.6)
Years of experience	Less than 1 year	33	(9.4)
	1-5 years	225	(64.3)
	6-10 years	57	(16.3)
	11-15 years	18	(5.1)
	More than 15 years	17	(4.9)
Type of pharmacy	Independent pharmacy	188	(53.7)
	Chain pharmacy	78	(22.3)
	Hospital pharmacy	38	(10.9)
	Health center	46	(13.1)
Average number of patients served per day	Less than 50	167	(47.7)
	50-100	149	(42.6)
	101-150	23	(6.6)
	More than 150	11	(3.1)
Registration in the syndicate	Yes	330	(94.3)
	No	20	(5.7)
Working hours in the pharmacy per week	Less than 20 hours	78	(22.3)
	20-30 hours	106	(30.3)
	31-40 hours	75	(21.4)
	More than 40 hours	91	(26.0)
Participation in education programs	Yes, regularly	49	(14.0)
	Yes, occasionally	163	(46.6)
	No	138	(39.4)

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Table 2 Sample distribution by knowledge regarding pharmacovigilance and ADR reporting

General knowledge questions	**No.**	**(%)**
Familiarity with the term pharmacovigilance (n=350)		
Very familiar—I have a comprehensive understanding	44	(12.6)
Familiar—I have a basic understanding	133	(38.0)
Heard of the term—cannot define it	98	(28.0)
Never heard of the term	75	(21.4)
Familiarity with the term adverse drug reaction (ADR) (n=350)		
Very familiar—I have a comprehensive understanding	157	(44.9)
Familiar—I have a basic understanding	160	(45.7)
Heard of the term—cannot define it	24	(6.9)
Never heard of the term	9	(2.6)
Familiarity with the procedures and process for reporting and submitting ADRs (n=350)		
Very familiar—I have a comprehensive understanding	10	(2.9)
Familiar—I have a basic understanding	62	(17.7)
Heard of the procedures—Don't know how to submit report	83	(23.7)
Never heard of the procedures	195	(55.7)
Specific knowledge questions	**Correct response**	
	No.	**(%)**
Definition of pharmacovigilance (n=177)*	78	(22.3)
The purpose of pharmacovigilance (n=350)	186	(53.1)
Definition of ADR (n=317)*	194	(55.4)
Types of ADRs should be reported (n=350)	233	(66.6)
Location of international center for ADR monitoring (n=350)	28	(8.0)
Awareness of Iraqi national pharmacovigilance program (n=350)	66	(18.9)
Iraqi ADR regulatory body (n=66)*	58	(16.6)
Awareness of local Pharmacovigilance Program in Erbil (n=350)	43	(12.3)
Minimum requirement for an ADR report submission (n=350)	246	(70.3)
Common ADR monitoring method (n=350)	63	(18.0)
Time frame for Serious unexpected ADR reporting (n=350)	26	(7.4)

* The total number of responses is less than 350 because skip logic was used, allowing some participants to bypass certain questions based on their previous answers.

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The findings from the attitude domain reveals that about 54.9% of respondents exhibited a positive attitude and the remaining 45.1% had a negative attitude. Most participants firmly believed that ADR reporting is an essential professional obligation, enhances medication safety, and should occur spontaneously and routinely. Many participants, however, expressed their discontent with the existing ADR reporting mechanism in their nation. The details of the attitude responses are presented in Table 3.

Table 3 Sample distribution by attitude regarding pharmacovigilance and ADR reporting (n=350)

Attitude	Disagree/ Strongly disagree No. (%)	Neutral No. (%)	Agree/ Strongly agree No. (%)
Pharmacovigilance is an essential part of my professional responsibilities.	20 (5.7)	46 (13.1)	284 (81.2)
All major adverse effects are recognized before a medication is marketed.	234 (66.9)	46 (13.1)	70 (20.0)
I believe that reporting ADRs can make a difference in drug safety.	15 (4.3)	25 (7.1)	310 (88.6)
ADRs should be reported spontaneously on a frequent basis.	28 (8.0)	41 (11.7)	281 (80.3)
Additional training on ADR reporting would be beneficial for improving reporting practice	9 (2.6)	24 (6.9)	317 (90.5)
I feel that the current ADR reporting system my country adequately supports my efforts to ensure drug safety	173 (49.4)	118 (33.7)	59 (16.9)
To what extent do you agree that the reporting of ADRs be made mandatory for community pharmacists	31 (8.9)	61 (17.4)	258 (73.7)
The study program should incorporate pharmacovigilance as a core topic.	18 (5.1)	25 (7.1)	307 (87.7)
I do not believe I should report an ADR if I am unsure of the causation of the response and the medicine.	176 (50.3)	75 (21.4)	99 (28.3)
Reporting ADRs for over-the-counter drugs is not required.	268 (76.6)	33 (9.4)	49 (14.0)
Unexpected unserious ADRs should not be reported	220 (62.9)	58 (16.6)	72 (20.6)
I think only new drug ADRs should be reported.	298 (85.1)	30 (8.6)	22 (6.3)
I believe that only safe medications are permitted in the market.	248 (70.8)	51 (14.6)	51 (14.6)

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Results from practice section reveals that poor practices were demonstrated by the majority, which accounted for (58.6%). Furthermore, 37.4% of participants exhibited moderate practice, and only a small percentage of participants (4%) exhibited good practices. As shown in Table 4, slightly more than half of the participants (53.1%) indicated that they frequently observed patients experiencing ADRs with their medication. Nonetheless, the overwhelming majority of pharmacists (91.1%) have never submitted ADR reports to their local or national pharmacovigilance centers, and approximately three-quarters of participants (73.4%) have never educated other pharmacy staff to report ADRs despite observing them among patients in their daily practice.

Table 4 Sample distribution by practice regarding pharmacovigilance and ADR reporting (n=350)

Practice	Never No. (%)	Rarely No. (%)	Sometimes No. (%)	Often No. (%)	Always No. (%)
How frequently do you observe ADRs in your daily practice.	33 (9.4)	131 (37.4)	152 (43.4)	27 (7.7)	7 (2.0)
How often do you consult with other healthcare professionals regarding suspected ADRs.	131 (37.4)	94 (26.9)	83 (23.7)	29 (8.3)	13 (3.7)
How frequently do you educate patients about the importance of reporting ADRs.	37 (10.6)	73 (20.9)	134 (38.3)	72 (20.6)	34 (9.7)
How often do you educate other pharmacy staff to report ADRs.	257 (73.4)	61 (17.4)	23 (6.6)	8 (2.3)	1 (0.3)
How often do you review the latest guidelines on ADR reporting.	169 (48.3)	94 (26.9)	58 (16.6)	24 (6.9)	5 (1.4)
How frequently does your employer encourage ADR reporting.	238 (68.0)	72 (20.6)	25 (7.1)	9 (2.6)	6 (1.7)
How often do you read articles on Pharmacovigilance.	117 (33.4)	89 (25.4)	111 (31.7)	24 (6.9)	9 (2.6)
How often have you received training on ADR reporting.	262 (74.9)	56 (16.0)	29 (8.3)	3 (0.9)	0 (0.0)
How often do you report the observed ADR in your practice.	319 (91.1)	23 (6.6)	5 (1.4)	3 (0.9)	0 (0.0)
How often do you follow up on reported ADRs to check for any additional information or outcomes.	325 (92.9)	16 (4.6)	8 (2.3)	1 (0.3)	0 (0.0)

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The study reveals a statistically significant association between knowledge and attitude, as well as between knowledge and practice (*P* <0.001), but no statistically significant association was found between attitude and practice (*P* = 0.815). The results are presented in three tables below: Table 5, Table 6, and Table 7.

Table 5 Association between knowledge and attitude level among community pharmacists

Knowledge level	Attitude Level		Total	*P* Value
	Negative	Positive		
	No. (%)	No. (%)	No. (%)	
Poor	91 (54.8)	75 (45.2)	166(100)	<0.001
Medium	64 (39.3)	99 (60.7)	163(100)	
Good	3 (14.3)	18 (85.7)	21 (100)	
Total	158 (45.1)	192(54.9)	350 (100)	

Table 6 Association between knowledge and practice level among community pharmacists

Knowledge level	Practice Level			Total	*P* Value
	Poor	Medium	Good		
	No. (%)	No. (%)	No. (%)	No. (%)	
Poor	118 (71.1)	45 (27.1)	3 (1.8)	166 (100)	<0.001
Medium	78 (47.9)	75(46.0)	10(6.1)	163(100)	
Good	9 (42.9)	11(52.4)	1 (4.8)	21(100)	
Total	205 (58.6)	131 (37.4)	14 (4.0)	350 (100)	

Table 7 Association between attitude and practice level among community pharmacists

Attitude level	Practice level			Total	*P* Value
	Poor	Medium	Good		
	No. (%)	No.(%)	No. (%)	No. (%)	
Negative	90 (57.0)	62(39.2)	6 (3.8)	158(100)	0.815
Positive	115(59.9)	69 (35.9)	8 (4.2)	192 (100)	
Total	205(58.6)	131 (37.4)	14 (4.0)	350 (100)	

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Discussion

Community pharmacists are the most accessible healthcare professionals that interact with patients on a regular basis; their involvement is crucial in ADR detection, prevention, and reporting. To the best of our knowledge, this is the first study in Erbil to report community pharmacists' knowledge, attitude, and practice regarding pharmacovigilance and ADR reporting.

The study's findings reveal that 47.4% of pharmacists exhibited poor knowledge, 46.6% showed moderate knowledge, and only 6% have good knowledge. This observation is consistent with the findings from Jordan, where 58.7% of pharmacists demonstrated moderate overall knowledge, and merely 11% of responders achieved a good knowledge score.[9,10] However, partially aligns with findings from the United Arab Emirates (UAE), where approximately 50% of pharmacists possessed moderate knowledge. Nevertheless, in their study, the proportion of participants with good knowledge was higher, and the proportion with poor knowledge was lower (29.7% and 21.1%, respectively) compared to our findings.[11] These differences could be because different study groups have different levels of awareness, different healthcare infrastructure, different access to continuing education programs, or different pharmacovigilance training.

In the present study, only 22.3% and 55.4% of pharmacists accurately defined pharmacovigilance and ADR, respectively. These findings are consistent with those of previous studies in Jordan (25.5% and 69.7%) and Nepal (29.9% and 49.4%).[7,12] Nevertheless, this figure is significantly lower than those reported in other studies from Saudi Arabia and Lebanon, where up to 62.9% and 66.9% of respondents from Saudi Arabia and Lebanon, respectively, provided an accurate definition of pharmacovigilance.[2,13] Several factors, including variations in educational curricula or disparities in the emphasis on pharmacovigilance in professional training, may be responsible for the lower rate of correct pharmacovigilance definitions in this study. Conversely, the proportion of pharmacists who accurately defined ADRs in this study was comparable to the results of similar research (59% and 44.5%).[2,13] This findings imply that pharmacists are competent in identifying and delineating ADRs, but their knowledge of the more comprehensive concept of pharmacovigilance is less robust.

Addressing this gap through targeted educational programs could enhance the effectiveness of ADR reporting systems and ultimately enhance patient safety results.

Moreover, the current study indicates that more than half of the participants (55.7%) had never been apprised of the processes for submitting ADR reports in the country. Additionally, only 18.9% and 12.3% of participants were cognizant of the existence of the national pharmacovigilance program in Iraq and a local pharmacovigilance program in Erbil, respectively. This finding closely resembles an observation from Iraq, in which majority of participants were not familiar with the Iraqi Pharmacovigilance system.[8] Likewise, in Saudi Arabia, merely 17.2% of participants were aware of where to report ADRs.[2] Additionally, only 23.4% of pharmacists in Nepal were aware of the national pharmacovigilancecenter.[12] These findings may indicate insufficient program dissemination to community pharmacists, highlighting the necessity of formulating methods to enhance awareness of pharmacovigilance center availability across the country.

In terms of the attitude, the majority of participants expressed a favorable attitude toward the notion that reporting ADRs is a professional responsibility, and it will improve medication safety. Regarding overall attitude, more than half (54.9%) of participants demonstrated positive attitudes, while the remaining 45.1% exhibited negative attitudes. Similar overall positive attitudes have been observed in studies from other countries, such as

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Jordan, Saudi Arabia, and Egypt, where pharmacists provided positive attitudes; most pharmacists recognized the significance of ADR reporting in patient care and public health, underscoring their dedication to patient safety.[9,14,15] While it is promising that over 50% of participants in Erbil exhibited a positive attitude. Nonetheless, improvement is still possible. The modest degrees of positive attitudes might be explained by insufficient awareness campaigns, poor training, and less suitable reporting environment. These findings highlight the need of focused interventions, frequent educational seminars, and training courses in order to increase pharmacists involvement in pharmacovigilance activities and support positive attitudes.

Findings from practice section indicate that majority of pharmacists (58.6%) demonstrated poor practices. While more than half of participants (53.1%) reported observing ADRs in their daily practice, 91.1% have never submitted ADRs to pharmacovigilance centers. These results are in agreement with research conducted in Iraq, in which majority of participants had never reported any ADRs.[8] Similarly, Saudi Arabia, exhibited comparable deficiencies in its reporting practices where 53.8% of pharmacists had identified an ADR during their careers, however, only 21.9% of participants reported ADRs.[2] The restricted participation in ADR reporting may be the result of a lack of comprehension regarding the existence of local and national pharmacovigilance programs in the country, poor workplace motivation, and deficient formal training in completing ADR reports.

The study's findings indicate a statistically significant association between the knowledge of pharmacists and attitude levels, as well as a significant association between knowledge and practice levels (P <0.001). This suggests that a higher level of knowledge correlates with elevated levels of positive attitudes and improved practices. This conclusion aligns with other studies from the Saudi Arabia and UAE.[2,16] The present study indicated that there is no statistically significant association between attitude and practice level (P = 0.815). These findings suggest that having a positive attitude alone may not necessarily translate into good practice. This discrepancy could be attributed to barriers that prevent participants from effectively translating their attitudes into practice. For example, a study in the UAE showed that even though around half of participants have moderate knowledge and exhibited positive attitude, but overall ADR reporting practice was extremely poor, as (44.3%) of the pharmacists emphasized that they had observed and detected ADRs in their practice at least once. Nevertheless, none of the identified ADRs were reported.[11]

Conclusion

In conclusion, this study emphasizes that community pharmacists in Erbil city generally possess positive attitudes and moderate knowledge regarding pharmacovigilance and ADR reporting; however, their actual practice remains suboptimal. The reporting practice of pharmacists may be restricted by barriers like lack of awareness about local and national ADR reporting systems, insufficient training, and education. The promotion of improved pharmacovigilance practices could be achieved by addressing these barriers through enhanced educational programs, increased awareness campaigns, and improved regulatory framework.

Competing interests

The authors declare that they have no competing interests.

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