Hilla University College Journal For Medical Science

Manuscript 1107

Knowledge, Attitudes, and Practices Toward Pharmacovigilance and Adverse Drug Reaction Reporting Among Healthcare Professionals in Iraq: A Cross-Sectional Study

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ORIGINAL STUDY

Hilla Univ Coll J Med Sci

Knowledge, Attitudes, and Practices Toward Pharmacovigilance and Adverse Drug Reaction Reporting Among Healthcare Professionals in Iraq: A Cross-Sectional Study

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Abstract

Background: Pharmacovigilance is critical for approving medication safety; yet, underreporting of adverse drug reactions (ADRs) remains common.

Objectives: This cross-sectional study aimed to assess the knowledge, attitudes, and practices of healthcare professionals in Karbala and Babylon, Iraq, using a structured paper-based questionnaire.

Materials and Methods: This study utilized healthcare professionals in Holy Karbala and Babylon to explore their demographic profiles, pharmacovigilance knowledge, attitudes, and reporting practices.

Results: Among 194 participants, most demonstrated positive attitudes toward ADR reporting, but notable gaps in knowledge and reporting behavior were observed. Pharmacists showed significantly higher knowledge levels than other professions, and formal training was strongly associated with improved understanding and a greater willingness to report. Major barriers included insufficient training, a lack of reporting systems, and limited institutional feedback. Participants emphasized the need for educational programs and better integration of reporting tools.

Conclusion: The findings highlight the importance of strengthening training and system support to enhance pharmacovigilance practices.

Keywords: Pharmacovigilance, Adverse drug reactions, Healthcare professionals, Knowledge, Practice, Reporting barriers

1. Introduction

Drugs are substances that act on a biological system by interacting with the molecular components in the body called drug receptors to produce a powerful therapeutic effect, yet, they also have the risk of causing unwanted or harmful effects called adverse drug reaction [ADR] [1]. These reactions not only prolong the length of hospital stays and healthcare costs but may also result in serious events such as birth defects, life threatening conditions, permanent disability and even death. Globally, the rate of hospital admissions related to ADRs has been reported to range between 0.2% and 41.3%, with nearly one-third of these events considered preventable [2]. For example, a prospective hospital-based study found that approximately 14.7 % of inpatient episodes were related to adverse drug reactions (ADRs), highlighting the substantial contribution of ADRs to hospital

Received 20 January 2026; revised 1 April 2026; accepted 1 April 2026.
Available online 20 June 2026

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https://doi.org/10.62445/2958-4515.1107

admissions and the importance of continuous monitoring of drug safety [3].

The World Health Organization (WHO) defines pharmacovigilance (PV) as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems". The WHO and other regulatory authorities worldwide have long promoted drug safety as part of their quality assurance initiatives. In this context, one of the effective methods for identifying unrecognized drug adverse effects after marketing is the spontaneous reporting of ADRs by healthcare professionals [4]. Physicians, pharmacists, and nurses, therefore, play an important role in pharmacovigilance activities, as their continuous observation and reporting of drug-related adverse effects are essential for the early detection of safety signals and for protecting patients from avoidable harm. However, much research from different countries has demonstrated that knowledge and participation in pharmacovigilance activities differ widely among healthcare workers [5].

Many professionals are acquainted with the concept, yet they do not consistently convert their positive attitudes into regular reporting behavior, a pattern often referred to as the "knowledge–attitude–practice gap." Several challenges contribute to this problem, including insufficient training opportunities, limited access to the reporting system, unavailable feedback from health authorities, fear of repercussions, and workload pressures. Over the last few years, initiatives including educational workshops, a digital reporting platform, and a feedback -driven system have demonstrated the potential to strengthen the reporting culture, though their implementation remains inconsistent between institutions and regions [6–8].

In Iraq, studies on healthcare professionals' knowledge, attitudes, and activities toward pharmacovigilance remain limited. Despite the growing national efforts to enhance patient safety, reporting drug adverse effects is not optimally integrated into daily healthcare practice; therefore, the most important steps to improve drug safety monitoring in the country are to understand the current level of pharmacovigilance knowledge and recognize barriers to effective participation [9].

Accordingly, this research aims to assess the knowledge, attitudes, and practices of healthcare professionals associated with pharmacovigilance and drug adverse effect reporting in Iraq, to evaluate demographic and professional factors that may affect these aspects, and to identify practical strategies that could improve reporting behavior and enhance the national pharmacovigilance system. The findings of this study are expected to provide significant guidance for policymakers and educators seeking to optimize medication safety within Iraqi healthcare settings.

2. Materials and methods

2.1. Study design, setting, and participants

This cross-sectional study employed a self-administered, paper-based survey distributed between 15 July and 30 August 2025. The target population included physicians, pharmacists, nurses, and other healthcare professionals working in community pharmacies and primary health centers in the Iraqi provinces of Holy Karbala and Babylon.

A convenience sampling technique was employed to recruit participants with at least one year of professional experience. Questionnaires were collected from licensed healthcare professionals in Holy Karbala and Babylon. Returned surveys were screened for completeness before data entry.

2.2. Survey instrument

The survey consisted of three-page and paper-based questionnaire that had five sections, primarily composed of close-ended items with a few open-ended questions.

1. **Section 1: Demographics**
   Consisted of seven items on participants' personal and professional characteristics, such as age, gender, profession,and years of experience.
2. **Section 2: Knowledge of Pharmacovigilance**
   Consisted of five items assessing the understanding of the pharmacovigilance definition, knowledge of ADR, and identification of reportable reactions. This section evaluated baseline pharmacovigilance knowledge.
3. **Section 3: Attitude Toward Pharmacovigilance**
   Consisting of four items addressing perceptions of the essential role of reporting ADRs in ensuring medication safety, professional responsibility, its role in patient safety, and the value of integrating pharmacovigilance into medical and pharmacy education.
4. **Section 4: ADR Reporting practices**
   Consisted of four items that evaluate the actual practice, including prior encounters with ADRs, reporting behaviors, reasons for non-reporting, and reporting frequency.
5. **Section 5: Barriers and Suggestion**
   Included two items exploring perceived institutional barriers such as a lack of training, the absence of structured reporting systems,

fear of blame, and a heavy workload, as well as suggested strategies to strengthen pharmacovigilance practices such as training programs, system integration, and awareness activities.

2.3. Statistical analysis

All data were entered, cleaned, and analyzed using the SPSS version 26. Descriptive statistics, including frequencies, percentages, means, and standard deviations, were used to summarize participants' demographic and professional characteristics as well as their responses to survey items.

Chi-square tests of independence were applied to examine associations between categorical variables, such as demographic characteristics and knowledge, attitudes, or practice outcomes. A p-value of <0.05 was considered statistically significant.

2.3.1. Analysis of multiple-response items

For questions that allowed participants to select more than one option (multiple-response items), each option was treated as an independent dichotomous variable (1 = selected, 0 = not selected). These variables were analyzed separately to determine potential associations with participants' demographic or professional characteristics. This approach allowed identification of specific factors influencing participants' choices for improvement strategies, such as training and education or simplified reporting processes. Chi-square tests were conducted individually for each response option to assess whether selecting a particular improvement measure was significantly associated with variables such as profession, years of experience, or previous pharmacovigilance training. Only statistically significant associations were reported in the results section.

3. Results

A total of 194 healthcare professionals participated in the current study, encompassing physicians (5.7%), pharmacists (58.8%), nurses (23.7%), and others (11.9%). Most of them were aged between 20–29 years (72.2%) and had 1–5 years of experience (44.8%). Females represented 53.6% of the sample, and little more than half (51.5%) had received formal training in pharmacovigilance, as shown in (Table 1).

Table 1. Demographic characteristics of participants.

Variable	Category	Frequency (%)
Age (years)	20–29	140 (72.2)
	30–39	42 (21.6)
	40–49	8 (4.1)
	50–59	3 (1.5)
	>60	1 (0.5)
Gender	Male	90 (46.4)
	Female	104 (53.6)
Profession	Physician	11 (5.7)
	Pharmacist	114 (58.8)
	Nurse	46 (23.7)
	Other	23 (11.9)
Years of experience	<1 year	38 (19.6)
	1–5 years	87 (44.8)
	6–10 years	41 (21.1)
	>10 years	28 (14.4)
Workplace	Public hospital	102 (52.6)
	Private hospital	27 (13.9)
	Pharmacy	54 (27.8)
	Primary health center	11 (5.7)
Formal training in pharmacovigilance	Yes	100 (51.5)
	No	94 (48.5)

Most participants (62.4%) had heard of the term pharmacovigilance, and approximately three-quarters (72.7%) accurately recognized it as the monitoring of ADRs. In the same way, 73.2% accurately recognized ADR as adverse drug reaction. Awareness of the national ADR reporting system was documented by 52.1% of participants, and 73.2% believed that ADR reporting is the duty of all healthcare professionals. The overall attitude toward pharmacovigilance was positive. Nearly 86.1% of respondents agreed or strongly agreed that ADR reporting improves patient safety, and 93.3% believed pharmacovigilance should be included in medical and pharmacy curricula. In addition, 88.7% expressed a willingness to report ADRs if a clear reporting system were available. Although 59.8% of participants had encountered an ADR in practice, only 36.1% reported it.

The major causes for not reporting encompassed a lack of knowledge about how to report (7.7%) and the absence of reporting systems or forms (10.3%). Concerning reporting frequency, 33% had never reported ADRs, while only 11.9% reported them periodically. The main repeatedly observed barriers to effective pharmacovigilance were a lack of knowledge or training (62.4%), an absence of reporting tools or systems (54.6%), and a lack of feedback from authorities (41.2%). Participants recommended that training and education programs (75.3%) and the integration of reporting systems into hospitals (40.7%) would improve pharmacovigilance performance. Details of participants' knowledge, attitudes, practices, perceived barriers, and suggested improvement strategies are shown in (Table 2).

There was no statistically significant association between gender and awareness of pharmacovigilance ($p = 0.394$). However, there was a strong relationship between profession and knowledge level ($p = 0.004$), with pharmacists showing higher awareness compared to other professions. years of experience were

Table 2. Knowledge, attitudes, practices, and perceived barriers toward pharmacovigilance.

Variable	Category	Frequency (%)
Knowledge about Pharmacovigilance		
Have you heard of the term "pharmacovigilance"?	Yes	121 (62.4)
	No	73 (37.6)
What is pharmacovigilance?	Monitoring drug effectiveness	23 (11.9)
	Monitoring ADR	141 (72.7)
	Ensuring drug availability	4 (2.1)
	Do not know	26 (13.4)
What does ADR stand for?	Adverse drug response	19 (9.8)
	Adverse drug reaction	142 (73.2)
	Accurate drug reporting	13 (6.7)
	Do not know	20 (10.3)
Which ADRs should be reported?	Life-threatening (Yes)	115 (59.3)
	Life-threatening (No)	79 (40.7)
	Mild and common (Yes)	69 (35.6)
	Mild and common (No)	125 (64.4)
	All unknown or unexpected (Yes)	118 (60.8)
	All unknown or unexpected (No)	76 (39.2)
Are you aware of a national ADR reporting system in Iraq?	Yes	101 (52.1)
	No	93 (47.9)
Do you believe ADR reporting is the duty of all healthcare professionals?	Yes	142 (73.2)
	No	52 (26.8)
Attitude Toward Pharmacovigilance		
Do you think ADR reporting improves patient safety?	Strongly agree	95 (49.0)
	Agree	72 (37.1)
	Neutral	17 (8.8)
	Disagree	7 (3.6)
	Strongly disagree	3 (1.5)
Are you willing to report ADRs if a clear system is provided?	Yes	172 (88.7)
	No	22 (11.3)
Should pharmacovigilance be included in the medical/pharmacy curriculum?	Yes	181 (93.3)
	No	13 (6.7)
Practice of ADR Reporting		
Have you ever encountered an ADR in your practice?	Yes	116 (59.8)
	No	78 (40.2)
If yes, did you report it?	Yes	70 (36.1)
	No	46 (23.7)
If you did not report it, what was the reason?	Did not know how to report	15 (7.7)
	Did not think it was serious	3 (1.5)
	No reporting form/system	20 (10.3)
	Lack of time	4 (2.1)
How often do you report ADRs?	Never	64 (33.0)
	Rarely	60 (30.9)
	Sometimes	47 (24.2)
	Always	23 (11.9)
	Other	4 (2.1)
Barriers to Pharmacovigilance		
Lack of knowledge/training	Yes	121 (62.4)
	No	73 (37.6)
Lack of reporting system/tools	Yes	106 (54.6)
	No	88 (45.4)
No feedback from authorities	Yes	80 (41.2)
	No	114 (58.8)
Fear of blame or consequences	Yes	37 (19.1)
	No	157 (80.9)
Workload and time constraints	Yes	64 (33.0)
	No	130 (67.0)
Low priority in clinical settings	Yes	40 (20.6)
	No	154 (79.4)
No legal obligation to report	Yes	42 (21.6)
	No	152 (78.4)

(Continued.)

Table 2. Continued.

Variable	Category	Frequency (%)
Suggested Improvements		
Training and education	Yes	146 (75.3)
	No	48 (24.7)
Simplified reporting process	Yes	73 (37.6)
	No	121 (62.4)
Integration into hospital systems	Yes	79 (40.7)
	No	115 (59.3)
Awareness campaigns	Yes	55 (28.4)
	No	139 (71.6)
Legal requirements for reporting	Yes	62 (32.0)
	No	132 (68.0)

Table 3. Association between demographic characteristics and knowledge, attitudes, and practices toward pharmacovigilance (chi-square test).

Dependent variable	Independent variable	Category	Yes n (%)	No n (%)	P-value
Heard of pharmacovigilance	Gender	Male	59 (65.6)	31 (34.4)	0.394
		Female	62 (59.6)	42 (40.4)	
Heard of pharmacovigilance	Profession	Physician	5 (45.5)	6 (54.5)	**0.004***
		Pharmacist	83 (72.8)	31 (27.2)	
		Nurse	23 (50.0)	23 (50.0)	
		Other	10 (43.5)	13 (56.5)	
ADR reporting is a duty	Profession	Physician	9 (81.8)	2 (18.2)	0.053
		Pharmacist	78 (68.4)	36 (31.6)	
		Nurse	33 (71.7)	13 (28.3)	
		Other	22 (95.7)	1 (4.3)	
PV included in curriculum	Profession	Physician	11 (100.0)	0 (0.0)	0.728
		Pharmacist	106 (93.0)	8 (7.0)	
		Nurse	42 (91.3)	4 (8.7)	
		Other	22 (95.7)	1 (4.3)	
Encountered ADR	Profession	Physician	6 (54.5)	5 (45.5)	0.888
		Pharmacist	69 (60.5)	45 (39.5)	
		Nurse	26 (56.5)	20 (43.5)	
		Other	15 (65.2)	8 (34.8)	
Definition of PV correct	Profession	Physician	9 (81.8)	2 (18.2)	**0.003***
		Pharmacist	92 (80.7)	22 (19.3)	
		Nurse	27 (58.7)	19 (41.3)	
		Other	13 (56.5)	10 (43.5)	
Heard of pharmacovigilance	Years of experience	<1 year	23 (60.5)	15 (39.5)	0.966
		1–5 years	56 (64.4)	31 (35.6)	
		6–10 years	25 (61.0)	16 (39.0)	
		>10 years	17 (60.7)	11 (39.3)	
Encountered ADR	Years of experience	<1 year	16 (42.1)	22 (57.9)	**0.041***
		1–5 years	54 (62.1)	33 (37.9)	
		6–10 years	30 (73.2)	11 (26.8)	
		>10 years	16 (57.1)	12 (42.9)	
Reported ADR	Years of experience	<1 year	10 (62.5)	6 (37.5)	0.060
		1–5 years	27 (50.0)	27 (50.0)	
		6–10 years	24 (80.0)	6 (20.0)	
		>10 years	9 (56.3)	7 (43.8)	

* Statistically significant at $P < 0.05$ (Chi-square test was used).

significantly associated with encountering ADRs ($p = 0.041$), but not with awareness or actual reporting behavior. Participants with 6–10 years of experience were more likely to encounter ADRs compared to less experienced staff, Associations between demographic characteristics (gender, profession, and years of experience) and pharmacovigilance-related knowledge, attitudes, and practices are summarized in (Table 3).

Official pharmacovigilance training had a significant positive effect on participants' knowledge and practice. Those who had received training were more likely to have heard of pharmacovigilance ($p < 0.001$), to have encountered ADRs ($p = 0.016$), and to be willing to report ADRs if a clear system was presented ($p = 0.049$). Training also correlated significantly with awareness of ADR definitions and understanding of

Table 4. Association between pharmacovigilance training and knowledge, attitude, and practice among healthcare professionals (n = 194) knowledge, attitude, practice, barriers, and suggested improvement.

Variable	Category	Training in PV: Yes n (%)	Training in PV: No n (%)	P-value
Knowledge				
Have you heard of the term "pharmacovigilance"?	Yes	81 (81.0)	40 (42.6)	**<0.001***
	No	19 (19.0)	54 (57.4)	
What is pharmacovigilance?	Monitoring drug effectiveness	11 (11.0)	12 (12.8)	**0.002***
	Monitoring ADR	83 (83.0)	58 (61.7)	
	Ensuring drug availability	1 (1.0)	3 (3.2)	
	Not know	5 (5.0)	21 (22.3)	
What does ADR stand for?	Adverse drug response	11 (11.0)	6 (6.4)	**0.009***
	Adverse drug reaction	2 (2.0)	0 (0.0)	
	Accurate drug reporting	73 (73.0)	68 (72.3)	
	Not know	10 (10.0)	1 (1.1)	
Attitude				
Do you believe ADR reporting is the duty of all healthcare professionals?	Yes	71 (71.0)	71 (75.5)	0.476
	No	29 (29.0)	23 (24.5)	
Are you willing to report ADRs if a clear system is provided?	Yes	93 (93.0)	79 (84.0)	**0.049***
	No	7 (7.0)	15 (16.0)	
Do you think ADR reporting improves patient safety?	Strongly agree	54 (54.0)	41 (43.6)	0.621
	Agree	33 (33.0)	39 (41.5)	
	Neutral	8 (8.0)	9 (9.6)	
	Disagree	4 (4.0)	3 (3.2)	
	Strongly disagree	1 (1.0)	2 (2.1)	
Practice				
Have you ever encountered an ADR in your practice?	Yes	68 (68.0)	48 (51.1)	**0.016***
	No	32 (32.0)	46 (48.9)	
If yes, did you report it?	Yes	46 (67.6)	24 (50.0)	0.056
	No	22 (32.4)	24 (50.0)	
How often do you report ADRs?	Never	24 (24.0)	40 (42.6)	0.053
	Rarely	34 (34.0)	26 (27.7)	
	Sometimes	28 (28.0)	19 (20.2)	
	Always	14 (14.0)	9 (9.6)	
Barriers				
Lack of knowledge/training	Yes	31 (31.0)	42 (44.7)	**0.049***
	No	69 (69.0)	52 (55.3)	
Lack of reporting system/tools	Yes	47 (47.0)	41 (43.6)	0.636
	No	53 (53.0)	53 (56.4)	
No feedback from authorities	Yes	66 (66.0)	48 (51.1)	**0.035***
	No	34 (34.0)	46 (48.9)	
Suggested improvements				
Training and education	Yes	23 (23.0)	25 (26.6)	0.562
	No	77 (77.0)	69 (73.4)	
Simplified reporting process	Yes	64 (64.0)	57 (60.6)	0.629
	No	36 (36.0)	37 (39.4)	

* Statistically significant at $P < 0.05$ (Chi-square test was used).

pharmacovigilance concepts ($p = 0.002$ and $p = 0.009$, respectively), as shown in (Table 4).

4. Discussion

The current study evaluated the knowledge, attitudes, and practices of healthcare professionals toward pharmacovigilance among 194 participants. The finding that 62.4% had heard of pharmacovigilance while 37.6% had not underscores a moderate level of awareness but also demonstrates significant gaps in knowledge. This agrees with prior international research referring that many healthcare professionals are still unaware of pharmacovigilance systems or ADR-reporting processes [10]. The elevated awareness among pharmacists in our study is aligned with other studies observing that pharmacists commonly demonstrate stronger knowledge, attitudes, and practice profiles when compared with other professions [1].

Attitudinally, participants revealed a positive interaction toward ADR reporting and pharmacovigilance integration into curricula (93.3%). Such beneficial attitudes are crucial because attitude often comes before performance. Nevertheless, the practice data demonstrate a marked deficit: while 59.8% had encountered ADRs, only 36.1% reported them. This imbalance between attitude and practice is frequently pointed out in the literature as the "knowledge-attitude-practice gap" [11]. The presence of this gap may indicate that positive attitudes alone are inadequate; structural, procedural, and motivational factors must be discussed to transform attitude into action.

The recognition of barriers in the current study – specifically, lack of knowledge/training (62.4%), insufficient reporting systems/tools (54.6%), and lack of feedback from authorities (41.2%) – provides awareness of the underlying causes of inadequate reporting. These insights mirror those of universal documentation where full duties, anxiety of blame, and fragile organizational culture are repeated motifs [10]. Fundamentally, our study findings explain that training and education programes (75.3%) and integration of reporting systems into hospital workflows (40.7%) were the most preferred enhancement strategies. Such preferences inagreement with the report indicating that multi-modal interventions (education + system redesign + audit feedback) provide good ADR-reporting outcomes compared to education alone [12].

From an evaluative viewpoint, training in pharmacovigilance and professional background (i.e., being a pharmacist) developed as significant estimators of awareness and reporting behavior, whereas gender and years of experience demonstrated lower or no significant relation in most analyses. Similar findings have been reported in studies carried out among healthcare professionals in Asia and Europe, where educational programs significantly enhanced ADR reporting rates and attitudes toward pharmacovigilance [6, 13].

4.1. Strengths and limitations

This study includes more than one profession (physicians, pharmacists, nurses) and location (public hospital, private hospital, pharmacy, primary health center), supplying a wider expression within the region. Furthermore, the utilization of cross-tabulation and Chi-Square tests permitted the identification of key relations between variables. However, some limitations must be mentioned: the cross-sectional design prohibits causal reasoning; self-documented data may present response and recall bias; and the accessible sampling may restrict generalizability beyond the research environment. Future studies could utilize longitudinal designs, larger samples, qualitative components (interviews/focus groups) and intervention analysis to assess the influence of training or system adjustments.

5. Conclusion

Overall, this study shows that while attitudes toward pharmacovigilance among healthcare professionals are preferred, significant deficiencies are present in knowledge and actual ADR-reporting performance. The findings signify the need for combined educational, organizational, and regulatory approaches – specifically concentrated on non-pharmacist professionals – to improve pharmacovigilance system performance and patient safety.

Ethical approval

Participation was voluntary, and informed verbal consent was obtained from all respondents prior to data collection. No personal identifiers were documented, guaranteeing anonymity and confidentiality. Participants were informed of the study objectives and their right to reject or withdraw at any time. Formal ethical approval was not necessary since the study carried minimal risk and encompassed no sensitive personal data.

Funding

None.

Conflicts of interest

No conflict of interest.

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