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Evaluation of Healthcare Providers' Awareness, Perspectives, and Practices Regarding Pharmacovigilance: A Cross-Sectional Study in Iraqi General Hospitals

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ABSTRACT

Pharmacovigilance plays a crucial role in safeguarding patients by monitoring and managing adverse drug reactions (ADRs). This study explored the awareness, perceptions, and practical engagement of healthcare providers (HCPs) with pharmacovigilance and ADR reporting in Nineveh's general hospitals. A cross-sectional survey was administered to HCPs in Mosul's general hospitals. The questionnaire was divided into four parts, collecting demographic details and assessing knowledge, attitudes, and practices related to pharmacovigilance. Out of 391 respondents, 242 recognized the purpose of pharmacovigilance, yet only 167 could define it accurately. ADR reporting was performed by 126 HCPs, although 329 expressed readiness to adopt reporting procedures. Differences in professional roles significantly affected both knowledge and practice scores, with pharmacists achieving the highest levels ($p < 0.001$). The findings indicate substantial gaps in pharmacovigilance knowledge among HCPs and widespread underreporting of ADRs, highlighting the need for strengthened training and institutional support to enhance reporting practices.

Keywords: Underreporting, Drug safety, Adverse drug reaction, Iraqi general hospitals

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Introduction

Adverse drug reactions (ADRs) are defined by the World Health Organization [1] as harmful and unintended effects occurring at normal therapeutic doses used for disease prevention, diagnosis, treatment, or physiological modulation. Although drugs undergo rigorous testing for safety and efficacy before market approval [2], unforeseen ADRs may emerge once medications are widely administered outside the controlled conditions of clinical trials [3].

ADRs pose a serious challenge to global health systems, contributing to increased morbidity, mortality, and financial burden [4]. Studies estimate that ADRs account for 0.3%–11% of hospital admissions and can prolong up to 10% of inpatient stays [5]. Despite their largely preventable nature, ADRs remain among the leading causes of death in many countries, ranking fifth in the United States according to meta-analytic data [6, 7]. Early identification of ADRs is vital for protecting patients, optimizing drug safety, reducing healthcare costs, and informing regulatory decisions [8].

Pharmacovigilance (PV) is the discipline focused on detecting, assessing, understanding, and preventing adverse effects or other drug-related problems [9]. The primary objectives of PV are to enhance patient safety, evaluate the risk–benefit profile of medications, and disseminate safety information to both healthcare providers (HCPs) and the general public [10]. ADR reporting constitutes the core mechanism of PV, providing essential information for identifying potential drug-related risks and guiding mitigation strategies [11].

Healthcare providers are crucial for the functioning of PV systems because patients rarely report ADRs directly to pharmaceutical companies, relying instead on their physicians, pharmacists, or nurses [12]. HCPs are responsible for promptly recognizing ADRs, documenting relevant details, and submitting reports to regulatory

authorities to ensure safe medication use [13]. A robust PV system depends on active participation from HCPs and effective communication with national PV centers [14].

Underreporting of ADRs is a worldwide problem, particularly in low- and middle-income countries [15]. Iraq has faced prolonged instability, and Mosul was severely affected by the 2016 ISIS offensive, which destroyed around 70% of the city's hospitals and impeded healthcare development [16]. Previous research has linked inadequate knowledge, attitudes, and practices among HCPs to insufficient ADR reporting [17-19]. Assessing HCPs' baseline understanding and behaviors is essential for designing targeted interventions to improve ADR reporting and strengthen PV systems by identifying gaps in practice [20-22].

Few studies have examined PV in Nineveh [23, 24], and none have comprehensively evaluated HCPs' knowledge, attitudes, and practices. Therefore, this study aimed to explore these aspects among physicians, pharmacists, and nurses working in general hospitals in Nineveh.

Materials and Methods

Study design, setting, and population

This research employed a cross-sectional, face-to-face survey using self-administered questionnaires among HCPs in Mosul City. The study included physicians, pharmacists, and nurses from three general hospitals: Al-Salam Teaching Hospital, Al-Mosul General Hospital, and Ibn Sina Teaching Hospital. Data were collected from November 2024 to April 2025. HCPs working at PV centers and healthcare students were excluded from participation.

Sample size and sampling

Approximately 2,000 physicians, pharmacists, and nurses were registered at the three hospitals. Using Raosoft's online calculator, a minimum of 377 participants was required for a 95% confidence level and 5% margin of error. To compensate for incomplete responses, the target sample size was set at 400. All eligible HCPs at the selected hospitals were invited to participate.

Questionnaire development

To design the study questionnaire, previously published studies assessing healthcare providers' (HCPs) knowledge, attitudes, and practices regarding pharmacovigilance (PV) and adverse drug reaction (ADR) reporting were reviewed [25-32]. Questions were adapted to align with the objectives of the present study and to fit the local cultural context. The questionnaire was then translated into Arabic using a standardized forward–backward translation process following Beaton *et al*.'s (2000) [33] guidelines, involving four translators. The research team reviewed all translations and finalized the Arabic version for validation.

A pilot test was conducted with 30 HCPs (10 physicians, 10 pharmacists, and 10 nurses), who were excluded from the main study, to ensure the questionnaire was understandable and accurately captured the intended information [34]. Experts evaluated the instrument for face and content validity, confirming its suitability. Internal consistency was acceptable, with Cronbach's alpha values of 0.729 for knowledge, 0.722 for attitudes, and 0.722 for practices.

Data collection tool

The finalized Arabic questionnaire included four main sections:

1. Demographics: Collected participants' age, gender, profession, educational level, and years of experience.
2. Knowledge: Comprised 14 multiple-choice questions assessing HCPs' understanding of PV and ADR reporting.
3. Attitudes: Included six Likert-scale questions to explore participants' perceptions and attitudes toward ADR reporting.
4. Practices: Contained six items (closed-ended and multiple-choice) to examine ADR reporting behaviors, prior training in ADR reporting, and participants' views on barriers to reporting.

Statistical analysis

All collected data were coded and analyzed using SPSS version 25. Descriptive statistics included medians, interquartile ranges (25th–75th percentiles), frequencies, percentages, and ranges. Inferential analyses were

performed using the Mann–Whitney U test and Kruskal–Wallis test, and Spearman correlation coefficients were calculated to evaluate associations between variables.

Ethical considerations

Approval was obtained from the Ethical Committee of the Health Directorate of Nineveh (Meeting No. 261, Research No. 2024210, 6th November 2024). Verbal informed consent was obtained from all participants, and confidentiality of responses was strictly maintained.

Results and Discussion

Participant demographics

Out of 400 invited HCPs, 391 completed the survey, corresponding to a 97.75% response rate. The majority of respondents were female (60.9%). Participants' ages ranged from 1 to 36 years of professional experience, with a median age of 28 years (IQR: 25–32) and a median experience of 2 years (IQR: 1–6). Most participants held a bachelor's degree (90%), whereas 4.3% had a master's degree and 5.6% held a PhD. Regarding the workplace, 47.3% worked at Al-Salam Teaching Hospital, 24.6% at Al-Mosul General Hospital, and 28.1% at Ibn Sina Teaching Hospital. Nurses made up 41.7% of the sample, pharmacists 38.6%, and physicians 19.7%.

Table 1. Demographic characteristics of study participants (n = 391)

Parameter	Category	Frequency	Percentage (%)
Gender	Male	153	39.1
	Female	238	60.9
Profession	Physician	77	19.7
	Pharmacist	151	38.6
	Nurse	163	41.7
Educational Level	Bachelor's	352	90.0
	Master's	17	4.3
	PhD	22	5.6
Workplace	Al-Salam Teaching Hospital	185	47.3
	Al-Mosul General Hospital	96	24.6
	Ibn Sina Teaching Hospital	110	28.1

Knowledge of pharmacovigilance and ADR reporting

Among the participants, 61.9% reported being familiar with the objectives of pharmacovigilance, yet only 42.7% could correctly define the term. Approximately 65% demonstrated an understanding of adverse drug reactions (ADRs), while 32.5% were aware of the existence of Iraq's national pharmacovigilance center. Notably, 26.6% of respondents were unable to identify any drugs that had been withdrawn globally due to ADRs **(Table 2).**

Table 2. Knowledge of pharmacovigilance and adverse drug reaction reporting among participants (n = 391)

Knowledge Item	Correct Response Frequency	Correct Response Percentage (%)
K1. Definition of pharmacovigilance	167	42.7
K2. Awareness of the purpose of pharmacovigilance	242	61.9
K3. Knowledge of medicines withdrawn due to ADRs	287	73.4
K4. Understanding of adverse drug reactions (ADRs)	254	65.0
K5. Awareness of which ADRs should be reported	306	78.3
K6. Knowledge that ADRs from drug–food interactions should be reported	327	83.6
K7. Misconception that only serious ADRs require reporting	202	51.7
K8. Misbelief that ADRs should be reported only after identifying the causative drug	123	31.5
K9. Awareness of ADR detection during clinical trials	39	10.0

K10. Knowledge of the year Iraq's pharmacovigilance center was established	127	32.5
K11. Knowledge of the location of the international ADR monitoring center	87	22.3
K12. Knowledge of the reporting timeline for serious ADRs in Iraq	28	7.2
K13. Identification of HCPs responsible for ADR reporting in hospitals	250	63.9
K14. Awareness of the information required in an ADR case report	305	78.0

Attitudes of healthcare providers

Table 3 presents the participants' attitudes toward ADR reporting. Nearly all respondents (96.9%) acknowledged the importance of reporting ADRs, and a similar proportion (96.6%) considered it a professional responsibility. Additionally, 92.1% emphasized the need for educational workshops on ADR reporting for healthcare providers. A substantial majority (84.1%) expressed readiness to incorporate ADR reporting into their routine practice, while 80.9% recognized that insufficient awareness exists regarding the reporting process. Finally, 77.7% of participants believed that ADRs contribute to increased healthcare costs.

Table 3. Attitudes toward adverse drug reaction reporting among study participants (n = 391), presented as frequency (percentage)

Attitude Statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
A1. ADR reporting is essential	273 (69.8)	106 (27.1)	7 (1.8)	3 (0.8)	2 (0.5)
A2. Reporting ADRs is a professional responsibility	257 (65.7)	121 (30.9)	10 (2.6)	2 (0.5)	1 (0.3)
A3. Detailed PV education should be provided to HCPs	202 (51.7)	158 (40.4)	24 (6.1)	7 (1.8)	0 (0)
A4. Willingness to incorporate ADR reporting into practice	124 (31.7)	205 (52.4)	42 (10.7)	18 (4.6)	2 (0.5)
A5. Awareness of the ADR reporting process is insufficient	107 (27.4)	209 (53.5)	53 (13.6)	16 (4.1)	6 (1.5)
A6. ADRs contribute to higher healthcare costs	99 (25.3)	205 (52.4)	51 (13.0)	27 (6.9)	9 (2.3)

Practices of healthcare providers

As summarized in **Table 4**, 62.9% of respondents reported having encountered ADRs in their professional practice; however, only 32.2% of those actually submitted ADR reports. Furthermore, just 35.5% of participants had received formal training on ADR reporting.

Table 4. Practices related to adverse drug reaction identification and reporting among study participants (n = 391)

Practice Aspect	Frequency	Percentage (%)
Identification of ADRs during practice	246	62.9
Access to ADR reporting forms	216	55.2
Submission of ADR reports	126	32.2
Number of ADRs reported		
– Fewer than 5	83	21.2
– Between 5 and 10	29	7.4
– More than 10	16	4.1
Previous training in pharmacovigilance	139	35.5

Barriers to ADR reporting

Participants identified the primary obstacle to ADR reporting as insufficient information provided by patients (39.1%), followed by limited awareness-raising or encouragement from regulatory authorities (24.0%), and uncertainty about the proper procedures and reporting channels (20.7%). Time limitations were reported less often (12.0%), highlighting that knowledge-related factors are the main challenges to effective ADR reporting **(Table 5).**

Table 5. Perceived barriers to adverse drug reaction reporting among study participants (n = 391)

Barrier Description	Frequency	Percentage (%)
Insufficient information provided by patients	153	39.1
Limited time to report	47	12.0
Uncertainty about reporting procedures or channels	81	20.7
Lack of active promotion by regulatory authorities	94	24.0
Other reasons	16	4.1

Differences in knowledge, attitudes, and practices among healthcare provider groups

Table 6 highlights variations in knowledge, attitudes, and practices related to pharmacovigilance (PV) and ADR reporting across different groups of healthcare providers categorized by gender, profession, and educational level. Regarding gender, knowledge scores were similar for males and females; males had slightly higher attitude scores, though this difference was not statistically significant (p = 0.297), while females demonstrated significantly higher practice scores (p = 0.007). Significant differences were observed across professional groups, with pharmacists achieving higher knowledge and practice scores than both physicians and nurses. Although weak positive correlations were identified between age and experience with knowledge, attitudes, and practices, these relationships were minimal in strength **(Table 7).**

Table 6. Differences in knowledge, attitude, and practice by gender, education, and profession.

Variable	Education level	Profession	Gender
Number (%)	Bachelor's: 352 (90.0%)	Physicians: 77 (19.7%)	Males: 153 (39.1%)
	Master's: 17 (4.3%)	Pharmacist: 151 (38.6%)	Females: 238 (60.9%)
	PhD: 22 (5.6%)	Nurses: 163 (41.7%)	
Knowledge score	7.0 (6–9)	7.0 (6–9)	7.0 (5–8)
Median (interquartile range)	8.0 (5–8)	8.0 (7–10)	7.0 (6–9)
	8.0 (7–10)	6.0 (4–7)	
P-value	0.112	<0.001*	0.456
Attitude score	26.0 (24–27)	27.0 (25–28)	26.0 (24–28)
Median (interquartile range)	27.0 (24–28)	26.0 (24–28)	26.0 (24–27)
	27.0 (25–29)	26.0 (24–27)	
P-value	0.286	0.069	0.297
Practice score	2.0 (1–4)	1.0 (1–2)	1.0 (1–3)
Median (interquartile range)	3.0 (1–6)	3.0 (2–5)	2.0 (1–5)
	1.0 (1–3)	1.0 (1–3)	
P-value	0.218	<0.001*	0.007*

*p-value is significant.

Table 7. Correlations between the age and years of professional experience with the knowledge, practice, and attitude scores.

Variable	Knowledge, rho (p-value)	Attitude, rho (p-value)	Practice, rho (p-value)
Age	0.194 (<0.001*)	0.134 (0.008*)	0.160 (0.001*)
Years of practice	0.145 (0.004*)	0.063 (0.008*)	0.182 (<0.001*)

*p-value is significant.

Pharmacovigilance (PV) fundamentally depends on two critical elements: the prompt identification of adverse drug reactions (ADRs) and their timely reporting, both of which are essential for safeguarding patient safety and optimizing therapeutic outcomes. Unrecognized ADRs can result in serious complications, including extended hospital stays, ineffective treatment, or even mortality. Systematic ADR reporting allows regulatory bodies to detect safety signals, revise treatment guidelines, and implement risk mitigation strategies. Consequently,

equipping healthcare providers (HCPs) to actively participate in ADR reporting is vital for strengthening PV systems, ensuring safer clinical care, and protecting public health.

This study utilized a structured questionnaire to assess the knowledge, attitudes, and practices of HCPs regarding ADR reporting in three general hospitals in Mosul. The study achieved a high response rate of 97.75%, which aligns with participation rates reported in previous investigations [8, 14, 35, 36]. Overall, participants demonstrated limited knowledge of PV. Although 61.9% indicated awareness of PV's purpose, only 42.7% correctly defined it, a finding consistent with an Egyptian hospital study reporting 42.64% correct responses [37]. About 73.4% of respondents recognized that certain drugs have been withdrawn due to ADRs, 65.0% correctly defined ADRs, and 78.3% understood which ADRs require reporting—similar to findings from Saudi Arabia [14]. However, 68.5% believed ADRs should only be reported once the causative medication is identified. Awareness of Iraq's Pharmacovigilance Center was limited (32.5%), and only 22.3% knew that the international ADR monitoring center is located in Sweden, consistent with results from a study in Aden, Yemen [38]. Moreover, 92.8% of participants were unaware of the required time frame for reporting ADRs, a gap also noted among HCPs in Alexandria [11].

Regarding attitudes, most participants (96.9%) agreed or strongly agreed on the importance of ADR reporting, demonstrating positive perspectives. A comparable result was observed in Saudi Arabia, where 97.0% acknowledged the necessity of ADR reporting to enhance medication safety [39]. Similarly, 96.6% considered ADR reporting a professional duty, although another study reported a much lower proportion of agreement (39%) [40]. Most respondents (92.1%) felt that PV should be formally taught to HCPs, aligning with the 80.4% reported in a Jordanian cancer center [8]. Furthermore, 84.1% expressed willingness to apply ADR reporting in practice, yet 80.9% acknowledged a lack of sufficient knowledge and awareness about reporting procedures, indicating a disconnect between willingness and practical readiness. Additionally, 77.7% recognized that ADRs contribute to higher healthcare costs, reflecting awareness of the economic impact. Overall, while attitudes toward ADR reporting are positive, education and structural support are necessary to translate this willingness into effective reporting, with training likely to reinforce these attitudes and improve reporting rates.

In terms of actual practices, 62.9% of participants reported having identified ADRs in their practice, and 55.2% confirmed the availability of reporting forms in their units. Despite this, only 32.2% had formally submitted ADR reports to the PV center, demonstrating a significant gap between recognition and reporting, consistent with prior studies in Qatar (29.3%) [41], Saudi Arabia (32.1%) [42], and Pakistan (32.4%) [43]. Among those reporting ADRs, only 4.1% had submitted more than 10 reports, 7.4% had reported 5–10, and 21.2% had reported fewer than five ADRs during their practice. Formal training in ADR reporting was reported by only 35.5% of participants, comparable to other studies reporting 35.2% and 41.6% [40, 44].

According to the study participants, the key obstacles to ADR reporting included insufficient information provided by patients, inadequate promotion of pharmacovigilance and ADR reporting by authorities, uncertainty about reporting procedures and channels, and time constraints. Similar barriers have been reported in previous studies, along with additional factors such as the absence of reporting forms and concerns over legal implications [45-47].

Professional role significantly influenced both knowledge and practice scores in this study. Pharmacists achieved higher knowledge and practice scores than physicians and nurses ($p < 0.001$), consistent with findings from Qatar [47]. Greater involvement in PV activities also appeared to correlate with professional experience and age, likely because more experienced HCPs encounter a higher volume of ADRs and are consequently more familiar with reporting procedures and confident in applying them. In contrast, a study from Saudi Arabia reported no association between knowledge or practice scores and age or experience [29]. Female HCPs demonstrated significantly higher practice scores than their male counterparts, whereas research in Jordan reported the opposite trend, with males outperforming females in practice scores [8].

Enhancing ADR reporting requires a multifaceted strategy, incorporating educational initiatives and supportive institutional policies. Academic institutions should partner with healthcare authorities to design targeted training programs for HCPs, reinforced by clear guidelines, regulations, and inclusion of PV and ADR reporting concepts in undergraduate curricula. Strengthening communication across all levels of the healthcare system can further reinforce pharmacovigilance efforts. Additionally, health authorities play a critical role by providing educational sessions, practical training opportunities, and fostering a workplace environment that motivates HCPs to report ADRs accurately and consistently.

Strengths and limitations

A major strength of this study is that it is, to our knowledge, the first to assess knowledge, attitudes, and practices regarding pharmacovigilance and ADR reporting among HCPs in Mosul City, Iraq. Nevertheless, the study has certain limitations. Only HCPs from public hospitals were included, limiting generalizability to private healthcare facilities. Moreover, data were collected solely in Mosul City, preventing extrapolation to the entire Nineveh governorate. Finally, the cross-sectional design restricts the ability to infer causality.

Conclusion

The study highlights inadequate knowledge among HCPs and significant underreporting of ADRs, despite generally positive attitudes toward reporting. Male participants exhibited lower practice scores than females, while pharmacists demonstrated significantly higher knowledge and practice scores compared with physicians and nurses. Older and more experienced HCPs also achieved higher scores in both knowledge and practice. These findings underscore the need for targeted strategies to bridge gaps between knowledge and practice, thereby improving patient safety. The results will inform the development of a customized intervention to enhance the knowledge, attitudes, and practices of HCPs in Mosul, and further research is warranted to evaluate its impact on KAP outcomes.

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