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Original Article

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Exploring pharmacovigilance awareness and attitudes among healthcare practitioners in Iraq: insights from a survey-based study

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ABSTRACT

Introduction: Healthcare professionals' (HCPs) play a vital role in recognizing potential medication risks, which can lead to early interventions and positive patient outcomes. This study aims to evaluate the knowledge and attitudes of healthcare professionals regarding pharmacovigilance in Iraq.

Methods: This is a cross-sectional conducted from June 13, 2023, to February 18, 2024, involving 415 healthcare providers (137 physician, 103 pharmacists, and 175 nurses) selected through convenience sampling from three public hospitals. Data collection was done through an adapted questionnaire, and the data were analyzed using descriptive statistical techniques, and Chi-square/Fisher's exact tests. P-value ≤ 0.05 was determined as significant.

Results: The results showed while most participants correctly identified the purpose of pharmacovigilance (71.3%) with significant difference between groups (p=0.02), only about half (52.5%) correctly defined pharmacovigilance (p=0.21). Almost all participants (94.5%) agreed that reporting adverse drug reactions is necessary. However, there was inconsistency between this belief and actual experience, as only 18.8% reported having encountered an adverse drug reaction. Top 3 factors discouraging healthcare professionals from reporting adverse drug reactions included lack of knowledge, fear of litigation, and prolonged or complex administrative procedures.

Conclusions: There were significant knowledge and attitude gaps among healthcare professionals in various aspects of pharmacovigilance. This highlights the importance of addressing these knowledge gaps and barriers to improve pharmacovigilance practices in Iraq. Targeted training programs, simplified reporting procedures, and a culture of safety regarding medications should be prioritized to enhance the reporting of adverse drug reactions.

Keywords: attitudes, health care providers, iraq, knowledge, pharmacovigilance

Introduction

In the field of drug safety and effectiveness, pharmacovigilance (PV) is highly crucial. It involves tracking adverse drug reactions (ADRs), as well as other issues in the development, use, and monitoring processes for medicines and vaccines. PV is an essential aspect of ADR surveillance that encompasses detection, assessment, understanding, and prevention (Hamid *et al.*, 2022). According to the World Health Organization (WHO), PV is "the science and activities related to identifying, evaluating, understanding, and preventing adverse effects or any other drug-related problem" (WHO, 2021). The importance of PV increases with products being approved for use by the public, as some side effects will manifest only in a population with many diseases and over long periods (Jose *et al.*, 2021).

Safety surveillance for complementary and alternative medicine (CAM) is an integral component of drug/vaccine life cycle pharmacovigilance, which extends to complementary and alternative medicine (Cole *et al.*, 2022). Although safety evaluation occurs in different preclinical and clinical phases, randomized clinical trials (RCTs) also have their own limitations, such

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as limited patient numbers, stringent eligibility criteria, and short duration (Borbély *et al.*, 2022). Thus, post-marketing surveillance, known as PV (phase IV of drug development), plays an important role in ensuring the safety of patients (Alomar *et al.*, 2020).

Throughout history, many cases have highlighted the essential role of pharmacovigilance (PV) is saving lives – such as deaths caused by the use of chloroform as an anesthesia and the thalidomide tragedy that led to abnormal fetal development and deformities in 46 countries, a condition called phocomelia. These incidents provide concrete evidence for proper safety monitoring post-marketing, independently from any industry interest (Tantray *et al.*, 2023). Additionally, PV plays a crucial role in ensuring public health safety and the effectiveness of medications. Through PV practices, healthcare professionals have a role to play in recognizing potential medication risks that could lead to timely interventions and positive patient outcomes. Monitoring drug safety with PV not only ensures proper care but also helps the regulatory body fulfill its mandate while promoting the establishment of safer health practices (Kugener *et al.*, 2021)

The 20th century witnessed tremendous development in activities linked to PV as well as the concept behind such advancement in Arab countries. Nevertheless, due to the present reality, it is evident that substantial variations among countries within the region exists with some countries having a good PV system that processes important tasks while others do not just an existent PV system (Alshammari *et al.*, 2020, Garashi *et al.*, 2022a). In 2010, the Iraqi Ministry of Health (MOH) founded a Pharmaceutical Variety Center inside the Department of Technical Affairs Pharmacology; the Iraqi Pharmacovigilance Center (IPC) and is now member of Uppsala Monitoring Centre - World Health Organization (WHO-UMC) (Salih *et al.*, 2016).

Regarding the operations of the center, the PV team has done several activities related to Medical Device Reporting (MDR) and some part of this activities are Guiding Circulars and some of this activities are Communication Circulars. “Guidelines for the National Pharmacovigilance System in Iraq,” which was launched in 2012 to make health care workers involved in the campaign. Additionally, the circulars, which directed the manufactures of health commodities to inform the MOH on safety information related issues between 2016 and 2017, were issued. The IPC has built a collection of rule and guides such as guidelines on the Good Pharmacological Practice for Arabian countries, as well as internal circulars (Alshammari *et al.*, 2019).

The level of understanding and knowledge on the part of the healthcare providers about PV plays a key role in maintaining the quality of medicine safety In other materials related to this topic: Healthcare providers can make a huge difference by staying updated with the recent information on drug safety and in-turn maintaining a higher degree of vigilance in their patients for signs of adverse reaction occurrence (Yawson *et al.*, 2022).

However, despite the crucial role and interventions employed by healthcare providers in the PV, underreporting of ADRs and subsequent impact continue to pose a challenge. Trying to improve the reporting procedures, simplifying the communication channels and setting the basis of a culture of safety regarding the medication should be the priorities in this area. Collaboration of healthcare providers, authorities and pharmacovigilance centers is one of the important issues in ensuring that adequate and effective approach of medicine safety is fully implemented (Desai, 2022). This study aims to evaluate knowledge of health care providers regarding PV in Iraq.

Materials and Methods

Study Design, Setting, and Sample

A cross-sectional study was conducted during the period from 13th of June, 2023 to 18th of February, 2024. The study involves the participation of 415 health care providers (137 physician, 103 pharmacists, and 175 nurses). Participants are recruited through convenience sampling from three public hospitals (Al-Nasiriyah, Al-Hussein, and Al- Habboubi) in Thi-Qar governorate, Iraq.

Data collection

The questionnaire was adapted from (Alshammari *et al.*, 2015) with permission and modified to be more suitable for the Iraqi environment. It was reviewed by a panel of 9 experts (2 subspecialized physicians, 2 pharmacists, 2 administrators at IPC and 3 academic nurses), each with more than 8 years of experience in their respective fields. The Cronbach's a model is used to examine the questionnaire's reliability, and the results show a correlation coefficient = 0.79.

The questionnaire consisted of two parts, the first part involving some background information (e.g.: profession, hospital) while the second part includes 18 items to assess knowledge and attitude of health care providers along with 8 items involving factors that may encourage reporting of ADRs and 8 items involving factors that may discourage reporting of ADRs. Right answer was awarded (1) while any of the wrong answers were awarded (0).

Hospital staff received questionnaires via their continuing education departments. The initial questionnaire package explained the study's purpose, potential benefits, data confidentiality, and included a consent question. Researchers followed up three times (at 3, 5, and 7-day intervals) to collect the questionnaires. Incomplete or unreturned questionnaires were excluded from the final data set.

Table 1. distribution of study sample by demographics and profession (n=415)

Variables	Groups	Physicians		Pharmacists		Nurses	
		f	%	f	%	f	%
Gender	Male	49	35.8	38	36.9	69	39.4
	Female	88	64.2	65	63.1	106	60.6
Hospital	Al-Nasiriyah	57	41.7	38	36.9	98	56
	Al-Hussein	45	32.8	30	29.1	46	26.3
	Al- Habboubi	35	25.5	35	34	31	17.7
Department	Wards	71	51.8	52	50.5	97	55.5
	Emergency department	30	21.9	27	26.2	41	23.4
	Operation room	11	8.1	7	6.8	21	12
	Consultatory clinics	25	18.2	17	16.5	16	9.1

Statistical Analyses

The data collected during this study were analyzed through using of Statistical Package for the Social Sciences (SPSS 26.0). Descriptive statistical techniques were employed. The categorical data were analyzed using a Chi square or Fisher's exact tests. P-value ≤ 0.05 was considered significant.

Ethical consideration

An informed consent form asking if participants would want to participate in the present study or not was given to each one. Additionally, the Thi-Qar Health Directorate/Council of Ethics has granted official ethical approval (Ref. 10904 in 5/6/2023). Confidentiality and anonymity were rigorously ensured when processing the data.

Results

Sample characteristics

Table (1) shows the distribution of a study sample (N=415) by demographics and profession. The highest percentage of study sample (64.2%) was female and 35.8% was male. This trend was consistent across professions, with females comprising the majority in each group: 64.2% of physicians, 63.1% of pharmacists, and 60.6% of nurses. The largest proportion of participants came from Al-Nasiryiah, Al-Hussein, and Al-Habboubi teaching hospitals (41.7%), (32.8%), and (25.5%) respectively. This distribution was relatively similar across professions, with slight variations. Participants worked in various departments, with the majority (51.8%) coming from wards. Other departments represented included the emergency department (21.9%), operation room (8.1%), and consultatory clinics (18.2%). The distribution across departments varied somewhat by profession. For instance, a higher proportion of nurses (55.5%) worked in wards compared to physicians (51.8%) and pharmacists (50.5%).

Knowledge Assessment

Table 2 assesses healthcare professionals' knowledge of key pharmacovigilance concepts. While most participants correctly identified the purpose of pharmacovigilance (71.3%) with a significant difference between groups (71.5%, 74.8%, and 69.1% for physicians, pharmacists, and nurses respectively; p=0.02), knowledge gaps were evident in other areas. For example, only about half (52.5%) correctly defined pharmacovigilance (p=0.21), and even fewer understood specific aspects like post-marketing surveillance studies (41.2%, p=0.13), causality assessment scales (18.1%; p=0.16), and the phase of clinical trials for identifying rare ADRs (18.6%, p=0.08). Knowledge regarding reporting timelines and responsible bodies in Iraq was also limited (24.1%, p=0.07).

Table 2. Knowledge responses concerning pharmacovigilance

Items	Percentage of correct answers			Total n (%)
	Physicians	Pharmacists	Nurses	
The following is the best definition of pharmacovigilance: **The identification, evaluation, comprehension, and prevention of ADRs***	46.7	63.1	50.9	218 (52.5)
The most effective application of pharmacovigilance is: **To determine a drug's safety**	71.5	74.8	69.1	296 (71.3)
When new medications are introduced to the market, the safety of those products is tracked using the following type of study: **Post Marketing Surveillance (PMS) studies**	38.7	46.6	40.0	171 (41.2)
The most popular scale for determining an ADR's causation is: **Naranjo algorithm**	20.4	25.2	12.0	75 (18.1)
The subsequent stage of a clinical study is where rare ADRs can be found: **During phase-4 clinical trials**	19.7	33.0	9.1	77 (18.6)
Reporting a significant negative event in Iraq to the regulatory body must be within: **Fifteen calendar days**	27.7	42.7	10.3	100 (24.1)
The regulatory agency in Iraq in charge of overseeing ADRs is: **Iraqi Pharmacovigilance Center**	38.0	61.2	21.1	152 (36.6)
The Iraqi Ministry of Health's online database for reporting adverse drug reactions is called: **Vigiflow®**	24.8	51.5	6.9	99 (23.9)
The following is the location of the international center for adverse drug reaction monitoring (WHO ADRs database): **Sweden**	12.4	22.3	6.9	52 (12.5)

*** Bold indicates correct answers**

Table 3. Attitude of health care providers regarding pharmacovigilance

Items	Percentage of answers		
	Yes	No	Don't Know
The reporting of adverse drug reaction is necessary.	94.5	0.7	4.8
Have you ever come across with ADR?	18.8	27	54.2
I have been informed by pharmacy staff about reporting ADRs.	7	89.9	3.1
Does your organization have a procedure in place to identify drugs that are considered high-risk or high-alert, such as insulin, opiates and narcotics, anticoagulants, concentrated electrolytes, and others, as they have a narrow margin of safety or a larger potential for errors or other negative outcomes?	71.8	1.9	26.3
Do you think Pharmacovigilance should be taught in detail to healthcare professionals?	64.3	15.4	20.2

Attitude Assessment

Table 3 explores healthcare professionals' attitudes towards ADR reporting. Almost all (94.5%; p=0.31) agreed that reporting ADRs is necessary. However, there was inconsistency between this belief and actual experience, as only 18.8% reported having encountered an ADR. Notably, most participants (89.9%; p=0.09) reported not receiving information about ADR reporting from pharmacy staff, and most (71.8%; p=0.11) indicated their institutions have processes for identifying high-risk medications. Finally, a majority (64.3%; p=0.07) believed pharmacovigilance should be taught in detail to healthcare professionals.

Deterrent factors

Healthcare providers' responses reflected that the three factors with highest agreement percentage were Prolonged or complex administrative procedures of ADRs reporting, Lack of knowledge regarding ADRs, and Fear of litigation with 75.7%, 70.6%, and 51.6%, respectively.

Discussions

Pharmacovigilance, the science and activities related to detecting and preventing adverse drug effects, relies heavily on the knowledge and participation of healthcare providers. As they are often the first to observe potential drug safety issues in their patients, their ability to recognize, report, and understand these issues is crucial. Additionally, the knowledge and attitudes of healthcare professionals toward pharmacovigilance are strongly related to the level of reporting of ADR's (Al Rabayah and Al Rumman, 2019), and the participation of health professionals is essential in reporting suspected ADRs (Bepari *et al.*, 2019).

The healthcare professionals' level of knowledge related to pharmacovigilance was evaluated to identify both their strength and weakness. During the workshop, most participants were able to grasp the main ideas of pharmacovigilance. However, the details of particular drugs' monitoring showed considerable knowledge gaps among the participants. This was done in different areas for instance the definition of pharmacovigilance, post-marketing surveillance studies, etc. causality assessment of the ADRs, and identification of rare ADRs. In addition, there was also a deficiency in the awareness among the local population about the reporting procedures and the relevant bodies. The authors are in line with the results of the previous research, that indicated the importance of the belonging healthcare professional be well versed in pharmacovigilance (Güner and Ekmekci, 2019, Hussain *et al.*, 2021, Khan *et al.*, 2023).

Developing countries did not join the Programme for International Drug Monitoring (PIDM) until the 1990s or later (Garashi *et al.*, 2022b). Therefore, they have particular difficulties in developing strong pharmacovigilance systems that can produce data to guide healthcare practice and policy (Kiguba *et al.*, 2023), and lack of knowledge, prioritization, and monitoring of medication safety and a poor pharmacovigilance system contributing towards the under-reporting of ADRs is expected (Hussain *et al.*, 2021).

Additionally, the study showed that almost all healthcare professionals agreed that reporting adverse drug reactions is necessary. However, there was inconsistency between this belief and actual experience, as a little percentage reported having encountered an adverse drug reaction. This suggests that while healthcare professionals understand the importance of pharmacovigilance, they may not fully appreciate its relevance to their daily practices, and such disparities between beliefs and experience is not uncommon (Abdulsalim *et al.*, 2023).

Table 4. Factors discourage health care professionals from reporting ADRs

Factor	Strongly agree n (%)	Agree n (%)	Don't Know n (%)	Disagree n (%)	Strongly Disagree n (%)
Lack of knowledge regarding ADRs	78 (18.8)	215 (51.8)	26 (6.3)	81 (19.5)	15 (3.6)
No cash incentive	15 (3.6)	56 (13.5)	202 (48.7)	102 (24.6)	40 (9.6)
Too little time to submit an ADR report	110 (26.5)	89 (21.4)	37 (8.9)	155 (37.3)	24 (5.8)
A single unreported incident might not have an impact on the ADR database.	60 (14.5)	99 (23.9)	121 (29.2)	62 (14.9)	73 (17.6)
Determining whether or not ADR has happened is difficult.	28 (6.7)	82 (19.8)	202 (48.7)	71 (17.1)	32 (7.7)
Fear of litigation	88 (21.2)	126 (30.4)	81 (19.5)	107 (25.8)	13 (3.1)
Prolonged or complex administrative procedures of ADRs reporting	102 (24.6)	212 (51.1)	31 (7.5)	60 (14.5)	10 (2.4)
Hierarchical settings culture	41 (9.9)	93 (22.4)	231 (55.7)	42 (10.1)	8 (1.9)

Data from present study show that three fundamental deterrent factors with the highest percentage of agreement were the protracted and complex bureaucratic procedures of reporting ADRs, a deficiency in knowledge necessary for reporting ADRs, and fear of legal implications. These findings coincide with earlier studies that describe factors associated with the under-reporting of ADR among healthcare professionals. Beside the existence of obstacle such as increased managed reporting processes, incentive can be introduced in the system in order to improve drug reporting (Shanableh *et al.*, 2023) Routine activity interface was found to cause discouragement according to the study (Geeven *et al.*, 2022). Yawson *et al.* (2022) and Nadew *et al.* (2020) shows that the main factors that guide healthcare workers in reporting adverse events as little knowledge about ADR reporting procedures, the fear of litigation, fear of litigation or a mixture of these two are hallmarks for the barriers preventing workers reporting these events. Similarly, Al Dweik *et al.* (2017) and Mirbaha *et al.* (2015) state that bloated or drawn out administrative processes make the reporting of ADRs among healthcare professionals a difficult task.

The current study has several limitations, it covers a relatively small number of healthcare professionals which limits the generalizability of the results. Moreover, the study is based on survey data by medical professions that may be inaccurate and could lead to recall bias. Furthermore, the design is limiting the ability to identify the casual relationship of study variables. Also, the response bias may be present because participants involved in the study may have different knowledge and attitude compared to those who were not included.

Conclusion

This research has revealed major weaknesses in the understanding of basic concepts of pharmacovigilance among healthcare professionals. With regard to the necessity of reporting adverse drug reactions, there is a substantial percentage of people that hold this view, but it stands in strong contrast with the actual cases they were encountered with at the time. The implications of healthcare workers who are discouraged from reporting adverse drug reactions While the appreciating of the role of the pharmacovigilance education has been recognized, there still exist background in working out the mechanisms for presenting it in the curriculum. Overall, our research highlights the need for specialized educational programs that support ADR reporting, as well as the simplification of reporting procedures among healthcare workers in order to promote compliance.

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Availability of data and materials

Data and materials of this study are available upon reasonable request.

Authors' contributions

Both of the authors have contributed to all aspects of this study.

Declaration of Interest

No potential conflicts of interest.

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