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Knowledge and practice of Iraqi community pharmacists on national adverse events reporting and review of the constraints of drug safety reporting

Samer Shukur Mohammed [a, *], Wael Waleed Musatafa [b], Manal Mohammed Younus [c]

[a] Department of Pharmacology and Toxicology, Faculty of Pharmacy, Al-Rafidain University College, Baghdad, Iraq

[b] Department of Pharmacology and Toxicology, Faculty of Pharmacy, Al-Turath University College, Baghdad, Iraq

[c] Iraqi Pharmacovigilance Center, Ministry of Health, Baghdad, Iraq

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ABSTRACT

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Introduction: Pharmacovigilance aids in protecting patients from adverse drug effects. Community pharmacists can play a significant role in the reporting of adverse drug reactions (ADRs) due to their advantageous position in terms of direct contact with patients and medical specialization,
Objectives: To determine the pharmacists' awareness in Baghdad and attitude regarding the national adverse drug reactions (ADRs) system activities in Iraq and their knowledge about the spontaneous reporting system
Methods: In this study, a validated self-administered cross-sectional questionnaire was used. During the study period, the questionnaire was distributed to 278 community pharmacists who worked in Baghdad for 4 months.
Results: Out of 278 pharmacists who participated in this questionnaire, 250 pharmacists completed the questionnaire. About 57% of them were female with less than 10 years experience in retail pharmacies. The study showed that about 76% already had information about the term pharmacovigilance and the existence of a pharmacovigilance center in Iraq, but about half of them showed a low level of knowledge about the way of filling, reporting, and sending ADR reports. Furthermore, About 90% of them prefer new ways of filling the ADR reports like using special mobile apps, special QR codes, and more simplified adverse event forms.
Conclusion: The study revealed that the community pharmacists in Baghdad have a positive view on ADR and pharmacovigilance, but several barriers were revealed that could impede the Iraqi pharmacovigilance center activities regarding spontaneous reporting of health care professionals.

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* Corresponding Author
Samer Shukur Mohammed
E-mail: samer.shukur@ruc.edu.iq
Contact: +9647700168800

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Introduction

Pharmacovigilance is more than just spontaneous reporting, and the evaluation of commercially available drugs is more than pharmacovigilance alone. Positioning a drug typically occurs in the years following its introduction, when global experience has accumulated. Originally a minor component of drug regulation, pharmacovigilance has evolved into a significant endeavor. The provision of information required for the evaluation of the benefits and risks of drugs is a scientific challenge in the first instance. There are also significant ethical, logistical, legal, financial, and commercial restrictions. It is necessary to develop good pharmacovigilance practices to ensure that data are collected and utilized appropriately and for the intended purpose. pharmacotherapeutic decision-making, whether individual, regional, national, or international, is heavily influenced by the study of the benefits and risks of drugs. In addition, pharmacovigilance is becoming a distinct scientific discipline.

Rare but severe adverse reactions, chronic toxicity, use in special populations (such as children, women, the elderly, or pregnant women), and drug interactions are frequently unaccounted for in clinical trials (Meyboom et al., 1999). Consequently, post-marketing surveillance activities are crucial for the early detection of unexpected and/or severe adverse reactions. ADRs are common and cause a significant number of deaths annually.

Before approximately 170 years ago, pharmacovigilance did not yet have its current name. It is a structured activity in the professional health field with significant social and commercial implications aimed at monitoring the risk/benefit ratio of drugs, enhancing patient safety, and enhancing life quality. In this commentary, we describe the major milestones of pharmacovigilance up to the present day to comprehend all the steps that have characterized its historical evolution; from the earliest reports, which were essentially letters or warnings sent by clinicians to publishers of prestigious scientific journals, to the ultra-structured electronic registries of the present day (Mazzitello et al., 2013).

In 1961, the Australian physician McBride published a letter in which he suggested a link between congenital malformations in newborns and the hypnotic thalidomide, which was sold under a variety of brand names around the world. Numerous births of children with congenital deformities were associated with the use of thalidomide. It was available as a prescription and over-the-counter medication, as well as in numerous simple analgesic formulations (Fornasier et al., 2018).

In 1953, thalidomide was first synthesized, and in 1956, an intensive campaign was launched to promote the drug (under various brand names including Contergan, Distavel, and Softenon) in Germany, England (1958), and other countries (Van Grootheest, K, 2003).

Pharmacovigilance is more than just spontaneous reporting, and the evaluation of commercially available drugs is more than pharmacovigilance alone. Positioning a drug typically occurs in the years following its introduction, when global experience has accumulated. Originally a minor component of drug regulation, pharmacovigilance has evolved into a significant endeavor. The provision of information required for the evaluation of the benefits and risks of drugs is a scientific challenge in the first instance. There are also significant ethical, logistical, legal, financial, and commercial restrictions. It is necessary to develop good pharmacovigilance practices to ensure that data are collected and utilized appropriately and for the intended purpose. The study of the benefits and risks of drugs plays a significant role in pharmacotherapeutic decisions, whether they are individual, regional, national, or international. In addition, pharmacovigilance is becoming a distinct scientific discipline (Meyboom et al., 1999).

For millennia, mankind has been aware of both the beneficial and harmful properties of medical remedies. In recent years, serious adverse reactions associated with medical products have prompted regulatory changes and efforts to identify drug safety issues as early as possible. Sponsors and regulatory bodies use pharmacovigilance to detect harmful effects associated with medical products to identify potential risks and provide physicians with timely warnings (Meyboom et al., 1999).

Pharmacovigilance is the science and activities about the detection, evaluation, understanding, and prevention of adverse effects or other potential drug-related issues. Therefore, there is a need for Pharmacovigilance. Recent expansions include herbals, traditional and complementary medicines, biological blood products, medical devices, and vaccines. In addition, many other issues are relevant to the science, such as substandard medicines, medication errors, lack of efficacy reports, use of medicines for indications that are not approved and for which there is insufficient scientific basis, case reports of acute and chronic poisoning, assessment of drug-related mortality, abuse and misuse of medicines, and adverse interactions between medicines, chemicals, and foods (Jones JK, 2014).

Generally speaking, pharmacovigilance activities can be divided into three categories: regulatory, industry, and academia. The objective of regulatory pharmacovigilance is to provide the public with drugs that have a favorable benefit–harm profile. In this context, some problems associated with regulatory post-marketing surveillance will be discussed, followed by a description of the methods used to detect new ADRs and a pros and cons analysis of each technique.

Regulatory advancements have been made over the past few years. However, the effects of these modifications have yet to become apparent, and it has not yet been established whether they have improved pharmacovigilance conduct. To further establish pharmacovigilance as a science, academia must develop new methods that will strengthen the current system.

Pharmacovigilance, as it is practiced today, involves identifying new ADRs and, if necessary, taking regulatory actions to protect public health, such as revising the summary of product characteristics (SPCs) or removing the drug from the market. Little emphasis has been placed on the generation of data that can aid a healthcare professional or a patient in deciding whether or not to use a drug. The collection and dissemination of this information is an essential objective of pharmacovigilance (WHO, 2002).

The primary objective of pharmacovigilance is to provide an early warning signal by detecting new ADRs. In pharmacovigilance, a signal of suspected causality is defined as "information that suggests a new potentially causal association, or a new aspect of a known association, between an intervention and an event or set of related events, either adverse or beneficial, which would command regulatory, societal, or clinical attention, and is judged to be of sufficient likelihood to justify further investigation."

By whom Improve patient care and safety about the use of medicines and all medical and paramedical interventions; improve public health and safety about the use of medicines; contribute to the assessment of benefit, harm, effectiveness, and risk of medicines, encouraging their safe, rational, and more effective (including cost-effective) use; and promote understanding, education, and clinical training in pharmacovigilance (Harmark, 2008).

Methods

The research was conducted over 4 months from October 2022 to February 2023 in Baghdad. Out of 278 retail pharmacists who were provided with the initial survey forms,250 only completed the survey. A random sampling strategy was considered in distributing the questionnaire for both districts of Baghdad (i.e., Karkh and Rasafa). The questionnaire for the survey was adapted from a previous study (Salih et al., 2016)

administrative and/or assistant staff were excluded from the study and did not receive the questionnaire, this is done by requesting the pharmacist's identity card issued by the Iraqi Syndicate of Pharmacists. The questionnaire assessed the attitudes, perceptions, and limiting factors of healthcare professionals regarding ADR reporting. The final questionnaire contained 45 questions organized into three categories: The first section consisted of 5 questions covering demographic data, and the second section consisted of 26 questions about the respondent's knowledge of the ADRs reporting system and their behavior. These questions consisted of multiple-choice (strongly agree, agree, Neutral, disagree, strongly disagree) while the Third section consisted of 14 questions about the constraints faced by community pharmacists in Pharmacovigilance reporting, it was categorized into five answers (strongly agree, agree, Neutral, disagree, strongly disagree).

Descriptive statistics were used to illustrate the answers of pharmacists and their demographic data. The categorical variables were expressed as percentages and frequencies. To determine whether there is a significant difference between the categorical variables, the chi-square test was utilized.

Results

Out of 250 retail pharmacists who participated and completed this questionnaire, major of them were female (n=142 (57%)). 57% of them were under 30 years and 29% were middle age group between 30 and 40 years old. Also, the questionnaire revealed that 212 (85%) of participants were freshly graduated with less than 10 years experience in retail pharmacies and most of them had a bachelor's in Pharmaceutical science (n=238 (95%)). Table 1 illustrates the demographic of the participants

Table 1: The sociodemographic characteristics of the retail pharmacists in Iraq

		P-Value
Gender		0.03
Male	108(43%)	
Female	142 (57%)	
Age (years)		0.001
≤30	142 (57%)	
31-40	72 (29%)	
41-50	28 (11%)	
≥50	8 (3%)	
Length of practice (years)		
0-10	212 (85%)	0.001
11-20	21 (8.4%)	
21-30	10 (4%)	
≥30	7 (2.8%)	
Graduation degree		0.001
BSc	238 (95%)	
MSc	10 (4%)	
PhD	2 (1%)	

Knowledge and attitudes of community pharmacists regarding drug safety reporting

The study results revealed that about two-thirds of the participants (76%) had already heard about pharmacovigilance during their career, 90% of them

believed that Pharmacovigilance is a part of their duty and all of them were convinced that drug safety monitoring is crucial where about half of the participants (n=128 (51%)) did not believe that OTC medicines needed to be reported. However, About 90% of participants trusted that drug safety reporting should be done for serious adverse effects that lead to hospitalization, death, and disability.

Furthermore, the results showed that most of the participants believed that drugs used during pregnancy and breastfeeding must be reported especially those not indicated during these periods. In addition to that, the majority of the pharmacists who participated in this questionnaire agreed about the importance of reporting other drug safety reporting regarding abuse, misuse, overdose, lack of efficacy, and off-label use of medications. In contrast, some of the participants said that consulting the physician is important before sending the report to the health authority.

As regards medicine complaints, the participating pharmacists believed that reporting falsified medicines and drugs that have technical complaints is important to the companies while comparable numbers of participants about their decisions regarding recalling the product to local distributor without reporting.

Also, the results showed that about 90% of participants favored the presence of a special form, hotline, or special mobile application to report product technical complaints to local distributors.

Question	*Responses n (%)*				
	strongly agree	**Agree**	**Neutral**	**Disagree**	**Strongly disagree**
Already know about pharmacovigilance	53(21%)	138(55%)	21(9%)	27(11%)	5(2%)
Pharmacovigilance is part of pharmacist duty	117(47%)	106(43%)	27(11%)	0(0%)	0(0%)
believe that drug safety monitoring is important	202(81%)	48(19%)	0(0%)	0(0%)	0(0%)
It is important to know the complete case report before reporting ADR	85(34%)	154(62%)	5(2%)	5(2%)	0(0%)
It is not important to report ADR for OTC drugs in pharmacies	5(2%)	11(4%)	59(23%)	128(51%)	0(0%)
It is important to report all ADRs that lead to hospitalization	117(47%)	122(49%)	11(4%)	0(0%)	0(0%)
It is important to report any ADR that leads to a life-threatening condition	176(70%)	59(23%)	16(6%)	0(0%)	0(0%)
It is important to report any ADR that leads to persistent disabilities	138(55%)	96(38%)	16(6%)	0(0%)	0(0%)
Reporting is important for the use of any medication during pregnancy	181(72%)	53(21%)	0(0%)	5(2%)	0(0%)
Reporting is important for medications that are not indicated during pregnancy	128(51%)	106(43%)	11(4%)	5(2%)	0(0%)
Reporting is important for all medications used during breastfeeding	122(49%)	112(45%)	11(4%)	5(2%)	0(0%)
Reporting is important for medications that are not indicated during the Breastfeeding period	101(40%)	101(40%)	37(15%)	10(4%)	0(0%)
Reporting should be done to all medications that are misused by patients	101(40%)	122(49%)	16(6%)	10(4%)	0(0%)
Reporting should be done to all medications that are abused by patients	117(47%)	117(47%)	11(4%)	5(2%)	0(0%)
Reporting should be done to all medications that lack their efficacy during their use	69(28%)	128(51%)	48(19%)	5(2%)	5(2%)
Reporting should be sent to all medications that are mistakenly dispensed by the pharmacist or the physician	32(13%)	149(60%)	48(19%)	21(9%)	0(0%)

Table 2 shows the community pharmacist's knowledge and practice of pharmacovigilance

Reporting should be done to all medications that have un-anticipated beneficial effect	48(19%)	122(49%)	69(28%)	10(4%)	0(0%)
Reporting should be sent to all medications that are off-label used (not indicated in insert leaflet)	64(26%)	160(64%)	16(6%)	10(4%)	0(0%)
Consulting the physician is important before sending the report	64(26%)	69(28%)	74(30%)	37(15%)	5(2%)
Reporting products that have a technical problem is crucial (like missing tabs inside its sheet, fragile tabs,….etc)	74(30%)	138(55%)	37(15%)	0(0%)	0(0%)
Reporting false medications is important to the Iraqi PV center	80(32%)	133(53%)	37(15%)	0(0%)	0(0%)
Reporting product complaints to the company is important	80(32%)	128(51%)	37(15%)	5(2%)	0(0%)
Recall the complaint product to the local distributor and never report that complaint	43(17%)	74(30%)	27(11%)	80(32%)	27(11%)
Put hotline Phone No. is important for reporting product complaints to local distributors	101(40%)	80(32%)	64(26%)	5(2%)	0(0%)
A special app to report product complaints is needed for collecting all the local distributors in Iraq	101(40%)	122(49%)	27(11%)	0(0%)	0(0%)
A unified form to report product complaints is needed for all local distributors in Iraq	90(36%)	101(40%)	59(23%)	0(0%)	0(0%)

Constraints on Pharmacovigilance in Iraq

The pharmacists surveyed were asked about the factors that may prevent them from reporting an Adverse event. The study revealed that about 63% of respondents (n = 160) reported that they didn't know about the existence of a special form for ADR reporting. While 47% (n=117) felt they lacked sufficient clinical knowledge to fill the report. About 19% (n=48) saw that the report was complicated, and 60% (n=149) didn't know the destination for sending these reports. Also, the survey showed that community pharmacists believed that the reporting is time-consuming, 35% (n=85) were afraid of legal consequences behind ADR reporting while only 11% (n=27) were not interested in pharmacovigilance activities.

In addition to that, the study showed that half of the participants (53%, n=133) believed that the Ministry of Health spent little effort in acknowledging the importance of pharmacovigilance.

As regards the steps needed to improve society's awareness of ADR reporting. The following opinions are shared by retail pharmacists regarding improving the awareness of pharmacovigilance importance: 85% (n=213) of the participants prefer to specify a special website link to fill adverse events reports, 92% (n=128) of them believed that MOH should use specific social media bot link to report pharmacovigilance cases, 93% (n=234) of the participants convinced that use of the special mobile app can assist in ADR reporting while 85% (n=212) favored to share specific QR code to ease access to the reporting page. Table 3 shows the responses regarding barriers behind low reporting frequencies for pharmacovigilance cases.

Table 3: The responses regarding barriers behind low reporting frequencies for pharmacovigilance cases.

Question	Response n (%)				
	strongly agree	**Agree**	**Neutral**	**Disagree**	**Strongly disagree**
There are no reporting forms available	59(23%)	101(40%)	27(11%)	43(17%)	16(6%)

I do not know about filling out the report form	27(11%)	90(36%)	43(17%)	64(26%)	27(11%)
The reporting form is complicated	5(2%)	43(17%)	96(38%)	80(32%)	27(11%)
I don't know the address to send the report after filling	27(11%)	122(49%)	16(6%)	74(30%)	10(4%)
Reporting is time-consuming	32(13%)	48(19%)	27(11%)	112(45%)	32(13%)
I am not convinced about reporting Pharmacovigilance cases	16(6%)	43(17%)	32(13%)	128(51%)	32(13%)
I am not interested in reporting pharmacovigilance cases	0(0%)	27(11%)	21(9%)	154(62%)	48(19%)
I am afraid legally about reporting such cases	21(9%)	64(26%)	80(32%)	59(23%)	27(11%)
MOH has few activities for Pharmacovigilance awareness	90(36%)	43(17%)	27(30%)	43(17%)	0(0%)
MOH should share special website links to fill pharmacovigilance cases	128(51%)	85(34%)	27(11%)	5(2%)	5(2%)
MOH should use a special social media bot system to assist pharmacovigilance cases	122(49%)	106(43%)	16(6%)	5(2%)	0(0%)
MOH should launch a mobile app for reporting pharmacovigilance cases	133(53%)	101(40%)	16(6%)	0(0%)	0(0%)
MOH should use a special QR code to directly and easily report the cases	122(49%)	90(36%)	27(11%)	0(0%)	5(2%)

Discussion

Adverse drug reactions are one of the most important causes of morbidity and mortality for individuals and societies. A reporting system is the most effective method for producing signals to document any adverse drug reactions.

Since 2010, Iraq has had an established pharmacovigilance system and become a full member of the WHO international drug monitoring program (WHO, 2023). This system aims to collect information on drug reactions that occur in local territories. The system relies on the voluntary reporting of ADRs by hospital and retail healthcare professionals (Generali et al., 1995). This study provides baseline information regarding ADR encountered by community pharmacists in Baghdad.

In contrast to a previous study done in 2016 by Salih et.al, the findings of the study indicated that ¾ of Iraqi pharmacists who participated in this survey had a positive attitude towards ADR and already knew about the pharmacovigilance as a general term compared to only 35 % on a previous study (Salih et al., 2016). This may be attributed to their background knowledge in undergraduate pharmacy education or may be due to attending one of the external educational sessions held by a health authority or syndicate of pharmacy. This study also revealed that age, gender, and length of practice do not affect ADR reporting.

This revealed the efforts done by the Iraq PV center regarding awareness of the importance of spontaneous reporting which is considered an essential part of the pharmaceutical duties. The most frequent reasons claimed by respondents for not reporting ADRs were consistent with others mentioned in previous articles (Cheema et al., 2017; Alraie et al., 2016; Bahlol et al., 2022).

The most significant obstacles preventing pharmacists from reporting ADRs are a lack of knowledge regarding the recipient of spontaneous reports and the lack of reporting forms. These findings should encourage health authorities especially the Iraqi PV center to work on increasing awareness about the importance of spontaneous reporting and increase the accessibility and availability of reporting forms to encourage community pharmacists to report ADRs, it is crucial for health

authorities to make their addresses public and to make reporting forms available.

The results of this study highlight the critical need to educate and train community pharmacists on ADR reporting. Although a substantial number of respondents believe in the importance of the pharmacovigilance center work as a significant aid in the ADR reporting process, this perception was not promoted. These results should be interpreted with caution because almost all of the respondents were unfamiliar with the existence of a spontaneous reporting system in the country, in addition to the small sample size used for this survey. these attitudes, perceptions, and barriers could be significantly overcome through effective educational programs. In addition to that several obstacles can be overcome by different aspects through promoting pharmacovigilance activities of Iraq PV center on different attitudes regarding special website links, different social media accounts, and contracts with specific services and mobile apps to facilitate the progress of ADR reporting.

Conclusion

The study showed that most of the community pharmacists in Baghdad have good scientific knowledge about pharmacovigilance, but they are unfamiliar with the Iraqi reporting system and the activities of the Iraqi PV center. The findings of the study highlight the critical need for special education programs and good promoting activities to encourage community pharmacists to report ADRs.

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