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Research Article

Explore Adverse Drug Reactions (ADRs) reporting by clinical and community pharmacists in Duhok, Kurdistan region- Iraq: hampered and perspective

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Abstract

Background: Pharmacovigilance systems are crucial for monitoring, ensuring the safe use of medications, and reducing the frequency of adverse drug reactions (ADRs). They also raise awareness of the importance of reporting ADRs to healthcare systems.

Aim: Explore the hampered and perspective held by Duhok pharmacists, particularly those employed in hospitals and private pharmacy sectors, about pharmacovigilance and ADR reporting.

Methods: A cross-sectional study was carried out from 20 February to 20 March 2019 using a self-administered questionnaire that had been previously created and modified. The data were examined using SPSS version 20, a statistical application for social software.

Results: The majority of respondents, pharmacists, stated that it is their responsibility to report adverse drug reactions (ADRs), and that drug safety monitoring is crucial (91%). More than 85% of pharmacists agreed that ADRs that result in life-threatening situations and those that result in congenital abnormalities should be reported immediately. The majority of them, however, were unaware of the Iraqi pharmacovigilance system, had never reported any adverse drug reactions, were unable to get reporting forms, and lacked the clinical knowledge required to recognize ADRs.

Conclusion: Underreporting was the main issue identified by the study because the majority of respondents were unable to define the term "pharmacovigilance" correctly, but they were aware of ADRs and displayed a positive attitude toward ADR reporting despite the fact that the majority of them had never reported any ADRs. To raise pharmacists' knowledge and awareness of the ADR reporting procedure, however, required steps should be made to establish interventional programs.

Keywords

Duhok, hampered, perspective, adverse drug reactions, report

Introduction

Occasionally, one of the following patient outcomes is regarded as a serious adverse event. Adverse drug reactions occur regularly. Death, life-threatening conditions, initial or protracted hospitalization, disability-significant, ongoing, or life-altering alterations, impairment, damage, or disturbance of the patient's physiological functioning, or conditions

necessitating intervention to stop long-term impairment or harm (Passarelli et al. 2005; Hema and Bhuvana 2012).

ADRs account for 10% to 25% of admissions to hospitals or even to intensive care units, such as ceftriaxone allergy, where it was previously noted that many patients needed to be admitted to these units and that occasionally patient death occurred; however, this could have been avoided with a simple subcutaneous allergy test (Lazarou et al. 1998; Pirmohamed et al. 2004). Following the thalidomide catastrophe in the 1960s, the majority of nations created their general pharmacovigilance systems (Nisa, Zafar et al. 2018). On November 3, 2010, Iraq joined the WHO Program for International Drug Monitoring as the 102nd nation (Al-Jumaili et al. 2021).

In both the commercial and public sectors, adverse drug reactions (ADRs) are becoming frequently seen during routine hospital and pharmacy operations. There are many obvious morbidities, and since they increase mortality, the healthcare system is financially challenged. We can prevent unpleasant medication reactions if pharmacists and healthcare professionals in general pay close attention to the facts regarding negative pharmaceutical effects when a drug is provided to patients. Understanding ADRs can aid in preventing unreasonable use of an inappropriate medication. Therefore, there is an urgent need to increase knowledge about adverse drug reactions and medication monitoring among pharmacists as well as among physicians who write prescriptions for medications (Passarelli et al. 2005).

Post- and undergraduate pharmacists must be aware of pharmacovigilance due to the underreporting of ADRs. A pharmacist's undergraduate education is perhaps the optimum time to raise understanding and awareness of pharmacovigilance because this is the time when they will need it the most. Pharmacy students need to receive enough instruction on how to spot, avoid, and report ADRs (Rehan et al. 2012).

On the other side, a major issue in many nations, including our own country of Iraq, is the underreporting of adverse drug reactions (ADRs) by pharmacists. Lack of awareness and expertise of methods to recognize and report ADRs may be used to explain this. Therefore, the purpose of this study was to assess pharmacists' perspective and hampered toward pharmacovigilance in Duhok, Iraq.

Methods

A previously minor modified and produced questionnaire was used in a cross-sectional study that was conducted from February 20 to March 20, 2019; a formal sample procedure was not used for the survey itself. The survey assesses pharmacists in Duhok's perspective and hampered about adverse medication reactions.

The academic pharmacists at Duhok University's College of Pharmacy, together with those employed by private pharmacies and public hospitals, are the main subjects of this study. The questionnaire paper-based was verbally (self-administered) completed by the pharmacists after inviting them to participate in the study and outlining its objectives, and the information was then manually gathered.

The three-page questionnaire contained the following information: 9 items make up the first section of the survey, some of which cover social status preferences of the participating pharmacists (Allela et al. 2017).

In the second section, 15 questions are addressed to gauge pharmacist perspective on the Iraqi pharmacovigilance system and the ADR reporting form. Pharmacists are requested to respond using the following 5-point scale: (1="strongly agree," 2="agree," etc.). 3 is "neutral," 4 indicates "disagree," while 5 indicates "strongly disagree."

Additionally, the final section of the survey comprised 15 questions that employed a 5-point scoring system to determine the hampered Duhok pharmacists have in reporting adverse drug reactions. 2="agree," 3 is "neutral," 4 indicates "disagree," while 5 indicates "strongly disagree."

Information from the completed questionnaire was captured using a Microsoft Excel spreadsheet (Microsoft Office 2010). Software version 20 of the Statistical Package for Social Sciences (SPSS) was used to code and enter the data from the returned questionnaire. Descriptive statistics were used to examine each question's social status, perspective and hampered.

Results

Characteristics of a pharmacist

Between February 20 and March 20, 2019, 152 pharmacists in Duhok, Iraq, received the survey questionnaire. Only 92 pharmacists responded to the survey; the remainder were unmotivated to participate, citing a lack of time or interest in the study as well as the absence of an operational pharmacovigilance system in their nation. Iraq, on the other hand, has a working pharmacovigilance system.

A 11 forms were ignored because the questionnaire was either incompletely or completely unfilled. In order to conduct this study, 81 questionnaires with a response rate of 53% were used. 49.6% of the 49 pharmacists who responded were women.

The majority of pharmacists (71%) were between the ages of 23 and 29; the majority of them (89%) lacked a postgraduate degree, and the majority of those who did were academic pharmacists who graduated from Duhok University.

Pharmacovigilance is a term that only a small percentage of countable pharmacists are familiar with; for the majority of pharmacists, we define it for them (Table 1).

Pharmacist's perspective on ADR reporting

The majority of pharmacists (92%) agreed that drug safety monitoring is crucial for preventing side effects from medications, as well as for reporting ADRs that result in life-threatening circumstances (92%) and those that result in congenital abnormalities (88%).

Table 1. Pharmacists' characteristics (N=81).

Sociodemographic	No.	%
Gender		
Male	32	39.4
Female	49	60.6
Age		
23-29	57	71
30-39	16	20
>=40	7	9
Length of practice		
0-10	65	80
11-20	11	14
>20	5	7
No. participations in scientific events per year		
None	54	66.5
1-3	25	31.5
>3	2	2
Role in detecting ADR		
Yes	34	42
No	47	58
No. of ADR observed in last year		
None	49	60
1-2	20	24
>2	12	11
Did you report		
Yes	2	3
No	79	97
University of graduation		
Hawler Medical University in Erbil	65	80
Baghdad University	6	7
Mosul University	2	3
others	8	10
Educational level		
BSc	72	89
Master	8	10
PhD	1	1

Approximately 92% of pharmacists concurred that speaking with other pharmacists, doctors, or academicians who have training in the relevant fields is essential before reporting an adverse drug reaction, and 96% of pharmacists thought that reporting an adverse drug reaction should be the pharmacist's primary duty.

About 60% of pharmacists disagree with the assertion that ADRs and adverse drug reactions are interchangeable (Table 2).

Pharmacist reporting of ADRs is hampered by

Less than 20% of the pharmacists who responded simply said they didn't know if reporting forms were available or where they should be sent, which is why fewer pharmacists overall reported ADRs than they should have.

More than 35% of the pharmacists said that they lacked the clinical expertise necessary to recognize hazardous medication reactions. About 67% of the pharmacists questioned thought that decentralizing the pharmacovigilance center would boost the quantity and quality of reports among pharmacists, and about 50% of the pharmacists were sure that adverse drug responses were occurred by the medicine (Table 3).

Discussion

Even if centers are accessible, underreporting of ADRs will be a major factor in the failure of pharmacovigilance programs, necessitating intervention and teaching programs about pharmacovigilance for both undergraduate and graduate pharmacists (Tandon et al. 2015).

There are very few studies showing obstacles to pharmacists in Iraq reporting adverse drug reactions (ADRs) (Salih et al. 2016). In order to assess attitudes and impediments toward ADRs among pharmacists in Duhok, Iraq, this study was done.

The findings of the current study demonstrate that a significant issue for the underreporting of ADRs was pharmacists' ignorance about the existence of a pharmacovigilance system in Iraq and the availability of reporting forms for adverse drug reactions. Studies conducted in those nations, however, indicate that underreporting of ADRs is a widespread issue (Ahmad et al. 2013; Mahmoud et al. 2014; Alraie et al. 2016). Research of a similar nature conducted in Iraq likewise found that underreporting was a significant issue (Salih et al. 2016).

Table 2. Perspective to ADRs reporting by Pharmacists. (N=81).

Questions	Responses				
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1. A pharmacist's duty is to report adverse drug reactions.	52	25	4	0	0
2. I think it's critically to monitor drug safety.	60	16	5	0	0
3. Prior to reporting, it is required to validate if an ADR is connected to a specific medication.	39	32	10	0	0
4. ADRs involving OTC medications dispensed in my pharmacy do not need to be reported.	25	10	14	18	14
5. It's critical to record ADRs that result in hospitalization.	47	22	12	0	0
6. It's critical to report ADRs that result in a scenario where life is in danger.	67	8	6	0	0
7. It's crucial to report ADRs that result in a congenital defect.	65	7	9	0	0
8. It's crucial to report ADRs that result in persistent impairment or capacity loss.	53	17	11	0	0
9. It's to crucial disclose ADRs so that I can respond to any inquiries about my practice.	43	24	13	0	1
10. It's critical to report ADRs in order to demonstrate to patients that you value their concerns.	40	30	11	0	0
11. Before reporting an ADR, speak with another pharmacist.	46	27	7	1	0
12. Transferring the duty of ADRs reporting will be improved via a pharmacovigilance program for the pharmaceutical industry and academy.	32	23	14	3	9
13. It's crucial to address ADRs with a doctor or academician with training in this area.	53	19	9	0	0
14. ADR and an adverse drug event are the same.	9	8	16	28	20
15. Both patients and doctors gain from ADR reporting.	56	17	6	0	2

Table 3. ADRs reporting hampered (N=81).

	Questions	Responses				
		Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1.	There are no available reporting forms.	34	25	9	7	6
2.	I'm not sure where these reports are supposed to be sent.	22	34	10	11	4
3.	The reporting form is difficult to complete.	12	17	22	24	6
4.	Reporting requires a lot of time.	7	12	8	34	20
5.	All significant ADRs are found before to registration.	16	30	18	10	7
6.	Because I wish to publish the case on my own, I do not report ADRs.	5	3	10	40	23
7.	I don't think the report was handled confidentially.	5	22	21	23	10
8.	I worry about losing my patients' trust.	2	15	27	23	14
9.	I have a hard time admitting that the patient has been hurt.	6	13	18	22	22
10.	I worry about the stated ADR's legal culpability.	1	11	29	23	17
11.	I have no desire to report	5	14	20	25	17
12.	I lack the clinical expertise necessary to identify ADRs.	14	17	27	16	7
13.	I have no idea how to file an ADR.	10	18	22	21	10
14.	The quantity and caliber of reports from retail pharmacists would increase if the Pharmacovigilance Center were decentralized (i.e., spread throughout different centers).	32	22	19	4	4
15.	I'm not sure the pill is to blame for the adverse drug reaction.	7	8	16	22	28

Even though only a tiny percentage of pharmacists are aware that the reporting form exists, they said that they have never seen it and, even if they have, that they are unaware of how to handle these reports and the address to send it to. This is especially true among hospital pharmacists. They asserted that the cause of this is a dearth of clinical expertise and pharmacovigilance knowledge that is may be fairly offered both during undergraduate studies and after graduation.

They also stated that the syndicate of pharmacists, in addition to its members in the ministry of health, is too responsible for the underreporting of ADRs because there are no or less educational programs or frequent conferences to emphasize the necessity of pharmacovigilance and the stages of reporting. It was found that just 34% of the pharmacists who responded to the survey attended scientific conferences, and the majority of those who do come from outside Iraq and had never attended one there. Another problem is that patients don't report adverse drug reactions (ADRs) to hospitals or the pharmaceutical manufacturer because the numbers on the container package of a drug for reporting ADRs are ineffective in our country, patients don't know about it (after asking patients who regularly take drugs because of chronic diseases), and there is low patient awareness of reporting ADRs.

To address the problem of underreporting and its harmful effects on community health and financial costs, early interventions are therefore necessary. These early interventions include enhancing reporting via several channels, including the internet, pharmacist/nurse reporting, and direct patient reporting, as well as enhancing the education and training of healthcare personnel (Hazell and Shakir 2006).

The Ministry of Health (MOH) in the Kurdistan Regional Government in Iraq is currently working to establish pharmacovigilance centers in Duhok, Iraq. These centers will be connected to one another, and the pharmacists working there will receive training on steps to report adverse drug reactions and how to handle report when they are received from hospitals, health centers, pharmacies, etc (Al-Jumaili et al. 2021).

Any adverse drug reactions reporting form should typically include the following fundamentals: Patients, medication, unfavorable effect, and author/reporter of the report (Yadav 2008). The majority of pharmacists thought that reporting ADRs would be advantageous for patients as well as for medical professionals.

Contrarily, research emphasizes the need for decentralizing pharmacovigilance, which will enhance underreporting and prevent significant adverse drug reactions (ADRs) for safer drug usage (Begaud 1992; Abjaude et al. 2015). Few pharmacists thought that having a single pharmacovigilance center would improve the quantity and caliber of ADR reporting.

Pharmacovigilance about over-the-counter (OTC) medications that pharmacists dispense in pharmacies is crucial (Sinclair et al. 1999; Layton et al. 2002; Touiti et al. 2021). Lower than 50% of pharmacists thought it was crucial to ADRs reporting brought on by over-the-counter medications. To report adverse drug reactions (ADRs) brought on by OTC drugs that are dispensed in their pharmacy, however, around half of the pharmacists who responded have a positive perspective. They believe that it is crucial for pharmacists to be willing to report their mistakes and to do so without fear of facing legal repercussions after dispensing any OTC drug that results in an ADR, as this demonstrates to patients that their concerns are taken seriously.

More than half of pharmacists do not think ADRs and adverse drug reactions are the same thing. Adverse drug events (ADEs), also known as ADRs, are defined as patient harm or injury brought on by a medical procedure that is not necessarily related to a drug, regardless of whether a pharmaceutical process error occurs. ADRs are negative pharmacological effects on people that happen at dosages that are typical for illness management, including prophylaxis, prevention, diagnosis, and therapy. It encompasses

both those that lead to hospitalization and those that develop while a patient is in the hospital (Jerschow et al. 2014).

Less than 15% of pharmacists are not sure that adverse drug reactions are caused by medications, and other factors that can cause adverse drug reactions include the use of additives, proper dosage, and appropriate self-medication.

Without naming the manufactured pharmaceutical company or disclosing the ADRs brought on by the drug, 33% of the clinical pharmacists claimed that they play a role in identifying ADRs, particularly among pharmacists working in hospitals. Examples of adverse drug reactions that the respondent pharmacists observed are as follows:

According to the responders, ceftriaxone vial injection causes severe adverse medication responses that can result in admission to an intensive care unit for a brief period of time. This reaction is brought on by a severe allergy to the injection, they claim. Third-generation cephalosporin antibiotic Ceftriaxone. Ceftriaxone has been linked to a number of negative side effects, including cardiac arrest and anaphylactic and anaphylactic reactions (Shalviri et al. 2012). Cephalosporins are regarded as the primary -lactams that trigger IgE-mediated reactions after penicillin (Romano et al. 2000). However, this allergic reaction can be avoided by performing a quick subcutaneous allergy test prior to injecting ceftriaxone in order to determine whether there is an allergic reaction or not and ensure the drug is administered safely.

Patients self-administer Dexon (dexamethasone) tablets and isotretinoin capsules. These drugs should be prescribed by a physician who is an expert in the field. As we know, before taking that drug, many tests should be done, such as LFTs, RFTs, lipid profile and CBC, etc. Because this medication has a wide range of adverse reactions, doctors only prescribe it when there is severe acne and other treatments are ineffective.

Combining proton pump inhibitors (omeprazole) and clopidogrel is another adverse drug reaction (ADR); omeprazole significantly reduces the anti-aggregation effect of clopidogrel on platelets (Drepper et al. 2012).

The ADRs that were primarily detected by clinical pharmacists, but there are undoubtedly significant and serious ADRs. This is primarily because pharmacists lack the clinical knowledge necessary to identify more complicated ADRs, as many pharmacists have claimed. In addition, some believe that there are not enough specialized pharmacists who are experts in that field.

94% of the respondents said that ADR reporting was a crucial component of the pharmacist's responsibility, and 68% of pharmacists believed that it was their obligation to the pharmaceutical business. It will be better to report when the pharmaceutical business is in charge of the pharmacovigilance program, especially for new medications. The aims of pharmacovigilance service (PV), which involves the pharmaceutical manufactures in addition to health care providers, is to ensure the safety of medicines in use with the primary objective of protecting the community, and other nations are now moving to adopt this goal (Hanzl-Dujmović et al. 2007).

Conclusions

This study can demonstrate the positive attitude Duhok pharmacists have regarding ADR reporting. Even though the majority of them had not reported ADRs previously, others were eager and interested in learning more after being informed of its purpose. The study identified underreporting of ADRs as a significant issue.

Recommendations

To find out whether variations in undergraduate study, health systems, and variations in pharmacist knowledge will affect the degree of reporting ADRs, a study involving a larger number of pharmacist participants is required. Other Iraqi governors should be included in this study, and the findings should be compared.

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