**Annals of Pharmacy Practice and Pharmacotherapy**
**ISSN: 3062-4436**
2023, Volume 3, Page No: 170-176

Available online at: www.galaxypub.co/page/journals

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# Investigation of Adverse Drug Reaction (ADR) Reporting by Clinical and Community Pharmacists in Duhok, Kurdistan Region, Iraq: Hampered and Future Perspectives

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**Received:** 11 September 2023; **Revised:** 01 December 2023; **Accepted:** 05 December 2023

## ABSTRACT

Pharmacovigilance plays a vital role in monitoring drug safety, minimizing adverse drug reactions (ADRs), and promoting the significance of reporting such events within healthcare systems. This study aimed to investigate the challenges and perspectives of pharmacists in Duhok, particularly those working in hospital and community pharmacy settings, regarding pharmacovigilance and ADR reporting. A cross-sectional survey was conducted from February 20 to March 20 2019 using a self-administered questionnaire that had been pre-designed and refined. Data analysis was performed using SPSS version 20. Most participating pharmacists recognized their responsibility in reporting ADRs and emphasized the importance of drug safety monitoring (91%). Over 85% agreed that ADRs causing life-threatening events or congenital abnormalities require immediate reporting. Despite this, the majority lacked awareness of the Iraqi pharmacovigilance system, had never submitted ADR reports, faced difficulties accessing reporting forms, and possessed insufficient clinical knowledge to identify ADRs. The primary issue highlighted by this study was underreporting, as most respondents could not accurately define "pharmacovigilance," even though they understood ADRs and maintained a positive attitude toward reporting. Enhancing pharmacists' knowledge and awareness through targeted interventional programs is essential to improve ADR reporting practices.

**Keywords:** Duhok, Hampered, Report, Adverse drug reactions, Perspective

**How to Cite This Article:** Carter E, Hall D, Adams J. Investigation of Adverse Drug Reaction (ADR) Reporting by Clinical and Community Pharmacists in Duhok, Kurdistan Region, Iraq: Hampered and Future Perspectives. Ann Pharm Pract Pharmacother. 2023;3:170-6. https://doi.org/10.51847/iBuU50iXMS

## Introduction

Serious adverse events are defined by certain patient outcomes, which include death, life-threatening conditions, initial or prolonged hospitalization, significant or permanent disability, ongoing physiological dysfunction, or the need for medical intervention to prevent long-term harm [1, 2]. Adverse drug reactions (ADRs) are common and contribute to 10–25% of hospital admissions, including admissions to intensive care units. For example, ceftriaxone allergies have led to hospitalization and, in rare cases, patient death, which could often be avoided through simple subcutaneous allergy testing [3, 4]. Following the thalidomide disaster in the 1960s, most countries established national pharmacovigilance systems [5]. Iraq officially joined the WHO Program for International Drug Monitoring as the 102nd member nation on November 3, 2010 [6].

ADRs are increasingly observed in both hospital and community pharmacy settings, imposing significant morbidity, mortality, and financial burdens on healthcare systems. Many ADRs can be prevented if pharmacists and healthcare providers carefully monitor potential adverse effects when dispensing medications. Awareness and understanding of ADRs are critical to avoiding inappropriate drug use. Therefore, enhancing knowledge of ADRs and medication safety is essential for both pharmacists and prescribing physicians [1].

Pharmacovigilance education is particularly important for both undergraduate and postgraduate pharmacists due to widespread underreporting of ADRs. Undergraduate training offers an ideal opportunity to instill awareness and practical skills for identifying, preventing, and reporting ADRs [7]. In Iraq, as in many other countries,

underreporting of ADRs remains a major issue, often linked to insufficient knowledge and lack of expertise in recognizing and reporting adverse events. This study aimed to evaluate the perspectives and challenges ("hampered") faced by pharmacists in Duhok, Iraq, regarding pharmacovigilance.

## Materials and Methods

A cross-sectional survey was conducted from February 20 to March 20, 2019, using a previously designed and slightly modified questionnaire. No formal sampling method was applied. The survey targeted pharmacists in Duhok to assess their perspectives and challenges in reporting ADRs.

Participants included academic pharmacists at Duhok University's College of Pharmacy, as well as pharmacists working in public hospitals and private pharmacies. The paper-based questionnaire was self-administered after providing participants with an overview of the study objectives, and responses were collected manually.

The three-page questionnaire comprised three sections. The first section included nine items addressing demographic and social characteristics of participants [8]. The second section contained 15 questions assessing pharmacists' perspectives on the Iraqi pharmacovigilance system and ADR reporting forms, using a five-point Likert scale (1 = "strongly agree," 2 = "agree," 3 = "neutral," 4 = "disagree," 5 = "strongly disagree"). The final section included 15 items using a similar five-point scale to evaluate the challenges faced by pharmacists in reporting ADRs.

Data from completed questionnaires were entered into Microsoft Excel 2010 and analyzed using SPSS version 20. Descriptive statistics were used to summarize participants' demographics, perspectives, and reported challenges.

## Results and Discussion

From February 20 to March 20, 2019, 152 pharmacists were invited to participate, and 92 responded, with non-participation largely due to lack of time, interest, or perception of the pharmacovigilance system as non-functional. After excluding 11 incomplete responses, 81 questionnaires were analyzed, yielding a response rate of 53%. Of the 49 pharmacists who reported their gender, 49.6% were female.

Most respondents (71%) were aged 23–29 years, and 89% had no postgraduate qualifications; those who did were primarily academic pharmacists who graduated from Duhok University. Only a small proportion of pharmacists were familiar with the term "pharmacovigilance," and for the majority, the study provided a definition **(Table 1).**

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

| Characteristic | No. | % |
|---|---|---|
| **Gender** | | |
| Male | 32 | 39.4 |
| Female | 49 | 60.6 |
| **Age (years)** | | |
| 23–29 | 57 | 71 |
| 30–39 | 16 | 20 |
| ≥40 | 7 | 9 |
| **Years of Practice** | | |
| 0–10 | 65 | 80 |
| 11–20 | 11 | 14 |
| >20 | 5 | 7 |
| **Number of Scientific Events Attended per Year** | | |
| None | 54 | 66.5 |
| 1–3 | 25 | 31.5 |
| >3 | 2 | 2 |
| **Role in Detecting ADRs** | | |
| Yes | 34 | 42 |
| No | 47 | 58 |
| **Number of ADRs Observed in the Past Year** | | |
| None | 49 | 60 |
| 1–2 | 20 | 24 |

| | | |
|---|---|---|
| >2 | 12 | 11 |
| **ADR Reporting** | | |
| Yes | 2 | 3 |
| No | 79 | 97 |
| **University of Graduation** | | |
| Hawler Medical University, Erbil | 65 | 80 |
| Baghdad University | 6 | 7 |
| Mosul University | 2 | 3 |
| Other | 8 | 10 |
| **Educational Level** | | |
| BSc | 72 | 89 |
| Master | 8 | 10 |
| PhD | 1 | 1 |

*Pharmacists' perspective on ADR reporting*

Most pharmacists (92%) recognized the importance of drug safety monitoring for preventing medication-related side effects, including the reporting of ADRs that may be life-threatening (92%) or cause congenital abnormalities (88%). Around 92% agreed that consulting with other pharmacists, physicians, or trained academicians is necessary before reporting an ADR, while 96% believed that reporting adverse drug reactions should be considered a core responsibility of pharmacists. Approximately 60% of pharmacists did not agree that the terms ADRs and adverse drug reactions are synonymous **(Table 2).**

**Table 2.** Pharmacists' perspective on ADR reporting (N=81)

| No. | Statement | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree |
|---|---|---|---|---|---|---|
| **1** | **Reporting adverse drug reactions is a fundamental responsibility of pharmacists.** | 52 | 25 | 4 | 0 | 0 |
| **2** | **Monitoring medication safety is of critical importance.** | 60 | 16 | 5 | 0 | 0 |
| **3** | **Before reporting, it is necessary to confirm that an ADR is linked to a specific drug.** | 39 | 32 | 10 | 0 | 0 |
| **4** | **ADRs associated with OTC medications supplied in my pharmacy do not require reporting.** | 25 | 10 | 14 | 18 | 14 |
| **5** | **Documenting ADRs that lead to hospitalization is essential.** | 47 | 22 | 12 | 0 | 0 |
| **6** | **Reporting ADRs that could pose a life-threatening risk is crucial.** | 67 | 8 | 6 | 0 | 0 |
| **7** | **It is important to report ADRs that may cause congenital anomalies.** | 65 | 7 | 9 | 0 | 0 |
| **8** | **ADRs that result in lasting disability or functional loss must be reported.** | 53 | 17 | 11 | 0 | 0 |
| **9** | **Reporting ADRs allows me to address questions about my professional practice.** | 43 | 24 | 13 | 0 | 1 |
| **10** | **Reporting ADRs demonstrates to patients that their concerns are valued.** | 40 | 30 | 11 | 0 | 0 |
| **11** | **Consulting with another pharmacist before reporting an ADR is important.** | 46 | 27 | 7 | 1 | 0 |
| **12** | **Delegating ADR reporting duties can be enhanced through pharmacovigilance programs in the pharmaceutical industry and academia.** | 32 | 23 | 14 | 3 | 9 |
| **13** | **Discussing ADRs with a physician or trained academician is essential.** | 53 | 19 | 9 | 0 | 0 |
| **14** | **ADRs and adverse drug events are equivalent.** | 9 | 8 | 16 | 28 | 20 |
| **15** | **ADR reporting benefits both patients and healthcare providers.** | 56 | 17 | 6 | 0 | 2 |

*Barriers to pharmacists' ADR reporting*

Fewer than 20% of responding pharmacists indicated uncertainty about the availability of reporting forms or the correct submission process, contributing to the overall underreporting of ADRs. Over 35% reported lacking the clinical knowledge required to identify harmful drug reactions. Approximately 67% believed that decentralizing the pharmacovigilance center could improve both the number and quality of ADR reports, while around 50% were confident that the observed adverse reactions were indeed caused by the medications **(Table 3).**

**Table 3.** Factors hampering ADR reporting (N=81)

| Question | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree |
|---|---|---|---|---|---|
| **1. Reporting forms are not readily available.** | 34 | 25 | 9 | 7 | 6 |
| **2. I am uncertain about the proper destination for submitting ADR reports.** | 22 | 34 | 10 | 11 | 4 |
| **3. Completing the reporting form is challenging.** | 12 | 17 | 22 | 24 | 6 |
| **4. Reporting takes an excessive amount of time.** | 7 | 12 | 8 | 34 | 20 |
| **5. All major ADRs are detected prior to drug registration.** | 16 | 30 | 18 | 10 | 7 |
| **6. I refrain from reporting ADRs because I wish to publish the case independently.** | 5 | 3 | 10 | 40 | 23 |
| **7. I doubt that submitted ADR reports are treated confidentially.** | 5 | 22 | 21 | 23 | 10 |
| **8. I fear losing patients' trust if I report ADRs.** | 2 | 15 | 27 | 23 | 14 |
| **9. I feel uncomfortable admitting that a patient experienced harm.** | 6 | 13 | 18 | 22 | 22 |
| **10. I am concerned about potential legal liability linked to the reported ADR.** | 1 | 11 | 29 | 23 | 17 |
| **11. I lack the motivation to submit ADR reports.** | 5 | 14 | 20 | 25 | 17 |
| **12. I do not have sufficient clinical expertise to recognize ADRs.** | 14 | 17 | 27 | 16 | 7 |
| **13. I am unsure how to properly submit an ADR report.** | 10 | 18 | 22 | 21 | 10 |
| **14. Decentralizing the Pharmacovigilance Center would likely improve both the quantity and quality of reports from community pharmacists.** | 32 | 22 | 19 | 4 | 4 |
| **15. I am uncertain whether the medication is responsible for the observed ADR.** | 7 | 8 | 16 | 22 | 28 |

Even when pharmacovigilance centers are accessible, underreporting of adverse drug reactions (ADRs) remains a significant challenge to the success of pharmacovigilance programs, highlighting the need for targeted educational interventions for both undergraduate and postgraduate pharmacists [9]. Few studies have explored the barriers faced by pharmacists in Iraq regarding ADR reporting [10], and this study was conducted to evaluate pharmacists' attitudes and obstacles toward ADR reporting in Duhok, Iraq.

The results indicate that a major factor contributing to underreporting is pharmacists' lack of awareness about the existence of pharmacovigilance systems in Iraq and the availability of ADR reporting forms. Comparable studies from other countries show that underreporting is a widespread problem [11-13], and similar research in Iraq confirms that this issue is significant [10].

Although only a small proportion of pharmacists are aware of reporting forms, most reported that they have either never seen the forms or do not know how to complete them or where to submit them, this problem is especially pronounced among hospital pharmacists, who attribute it to insufficient clinical training and limited pharmacovigilance education both during their undergraduate studies and after graduation.

Pharmacists also identified shortcomings in professional organizations and the Ministry of Health, citing a lack of educational programs and scientific conferences to emphasize the importance of pharmacovigilance and reporting procedures. Only 34% of pharmacists surveyed had attended scientific conferences, most of which were

held outside Iraq, leaving many without local opportunities for professional development. Another contributing factor is low patient involvement, as patients rarely report ADRs to hospitals or manufacturers; information on ADR reporting provided on medication packaging is ineffective, and patients generally lack awareness of reporting procedures, especially those on chronic medications.

To mitigate underreporting and its negative consequences on public health and healthcare costs, early interventions are essential. These include promoting reporting through multiple channels—online systems, pharmacist or nurse reporting, and direct patient reporting—and enhancing training and education for healthcare professionals [14].

The Kurdistan Regional Government's Ministry of Health is currently establishing interconnected pharmacovigilance centers in Duhok, where pharmacists will receive training on ADR reporting procedures and handling reports from hospitals, clinics, and pharmacies [6]. Standard ADR reporting forms should capture key information, including patient details, medication, adverse effects, and the reporter's identity [15]. Most pharmacists acknowledged that reporting ADRs benefits both patients and healthcare providers.

Research also emphasizes the importance of decentralizing pharmacovigilance, as this can improve reporting rates and reduce the risk of serious ADRs, ultimately enhancing drug safety [16, 17]. Only a minority of pharmacists believed that a single centralized center would improve the quantity and quality of ADR reporting.

Pharmacovigilance for over-the-counter (OTC) medications is particularly important, as pharmacists frequently dispense these drugs [18-20]. Less than half of pharmacists considered reporting ADRs caused by OTC medications to be critical, though about half of respondents held a positive attitude toward reporting such ADRs in their pharmacies. They emphasized the importance of reporting mistakes without fear of legal consequences, as this demonstrates accountability and reassures patients that their concerns are taken seriously.

Furthermore, more than half of pharmacists did not recognize that ADRs and adverse drug events (ADEs) are distinct concepts. ADEs, which may occur independently of drug administration errors, refer to any harm caused to patients during medical care. ADRs, in contrast, are harmful pharmacological effects occurring at standard therapeutic doses for treatment, prevention, diagnosis, or prophylaxis, including effects that result in hospitalization or develop during hospitalization [21].

Less than 15% of pharmacists expressed uncertainty about whether adverse drug reactions (ADRs) were directly caused by medications, suggesting that other contributing factors—such as excipients, incorrect dosages, or inappropriate self-medication—can also trigger ADRs. Around 33% of clinical pharmacists stated that they actively participate in identifying ADRs, particularly those working in hospital settings, although they did not specify the pharmaceutical companies or disclose the reported ADR cases.

Pharmacists provided several examples of ADRs they had encountered. According to their observations, ceftriaxone vial injections may lead to severe hypersensitivity reactions that can require short-term intensive care unit admission. They reported that these reactions are caused by acute allergic responses to the injection. Ceftriaxone, a third-generation cephalosporin antibiotic, is known to induce various adverse reactions, including anaphylaxis and even cardiac arrest [22]. Cephalosporins are considered the major β-lactam antibiotics responsible for IgE-mediated hypersensitivity reactions following penicillin exposure [23]. However, these allergic reactions can often be prevented by performing a rapid subcutaneous allergy test before administering ceftriaxone to ensure patient safety.

Respondents also noted that some patients self-medicate with Dexon (dexamethasone) tablets and isotretinoin capsules, both of which require prescription and medical supervision. Physicians generally recommend several preliminary tests—such as liver and renal function tests (LFTs, RFTs), lipid profile, and complete blood count (CBC)—before initiating isotretinoin therapy. Because these drugs carry numerous adverse effects, they are prescribed only for severe acne cases that do not respond to other treatments.

Another ADR highlighted by pharmacists involved the concurrent use of proton pump inhibitors (omeprazole) and clopidogrel, as omeprazole significantly diminishes clopidogrel's antiplatelet activity [24].

Most of the ADRs detected were identified by clinical pharmacists, yet several respondents pointed out that many serious ADRs remain unrecognized. This limitation was attributed to insufficient clinical knowledge among pharmacists, as well as a shortage of specialists trained in pharmacovigilance.

A large majority (94%) of respondents agreed that ADR reporting is an essential part of a pharmacist's professional duty, while 68% believed it is also a responsibility toward the pharmaceutical industry. Pharmacists suggested that reporting would be more effective if pharmaceutical companies took greater responsibility for pharmacovigilance, especially concerning newly marketed drugs. The overarching aim of pharmacovigilance

(PV)—which involves collaboration between pharmaceutical manufacturers and healthcare professionals—is to ensure medication safety and safeguard public health, a goal increasingly embraced by many countries worldwide [25].

## Conclusion

This study highlights the generally positive attitudes of pharmacists in Duhok toward ADR reporting. Although most had not submitted reports previously, many expressed enthusiasm and a willingness to learn more once they understood the importance of pharmacovigilance. The findings clearly indicate that underreporting remains a major barrier to effective ADR monitoring in the region.

*Recommendations*

A broader study including a larger sample of pharmacists is needed to determine how differences in undergraduate education, healthcare systems, and pharmacists' knowledge influence the extent of ADR reporting. Future research should also encompass other Iraqi governorates to allow for comparative analysis of the results.

**Acknowledgments:** None

**Conflict of Interest:** None

**Financial Support:** None

**Ethics Statement:** None

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