The Egyptian Journal of Hospital Medicine (January 2023) Vol. 90, Page 937-942

Detection of Main Barriers for Adverse Drug Reactions Reporting in The Middle East Countries: Review article

Mohammed Mahdi H. Abdul Hussein*, Jubran K. Hassan
Department of Clinical Pharmacy, College of Pharmacy, University of Basrah, Iraq
***Corresponding author**: Mohammed Mahdi H. Abdul Hussein, **Mobile:** 009647725579153, **E-mail:** smmh91@gmail.com

ABSTRACT

Background: For years, specialists have been interested on the verge of documentation of adverse drug reactions because of its great importance. The countries of the Middle East have also kept pace with this mission and developed in the past years. Like any other project, this documentation process is accompanied by several problems that will negatively affect the objectives set in this area.
Objective: The aim of the current study is to know the main barriers regarding the process of adverse drug reactions in the Middle East area.
Patients and methods: In October 2022, a manual search of the literary databases PubMed and Google Scholar has done. The 102 articles were manually screened. Studies that have been published between 2012 and 2022 were eligible.
Results: From the 102 publications that underwent manual screening, 26 research articles from 12 different countries qualified for inclusion in the study. Lack of enthusiasm, a professional atmosphere for the conduct of pharmacovigilance, a general lack of knowledge and awareness concerning pharmacovigilance and not enough time for reporting are the main barriers for adverse drug reactions.

Conclusion: According to the results, the lack of knowledge or awareness of pharmacovigilance practices and the absence of mechanisms that assist recording in terms of enough time, motivation, or the environment as a whole are the two most significant causes of underreporting.
Keywords: Adverse drug reaction, Barriers, Pharmacovigilance, health care providers, Review, University of Basrah.

INTRODUCTION

The use of medicines is an inextricable part of human life and we see clearly with the development of new diseases and health problems, the indications for the use of medicines have become more important and besides, the use and discovery of therapeutic substances to be in line with the need of humans to fight these diseases. Accordingly, with the widespread use of medicines in the world, also there has been a proliferation of adverse drug reactions (ADRs) associated with the use of those drugs. World Health Organization (WHO) has provided a definition of ADR, which is as follows: "a negative, unanticipated reaction to a medicine that happens at dosages typically used in humans for illness prevention, diagnosis, treatment, or altering physiological function". **Edwards [(1)].**

The term of pharmacovigilance (PV) is another important concept has taken a documented association with the ADRs since years ago and it is mean: "the science and actions related to the evaluation, detection, comprehension, and prevention of negative drug-related effects or any other issues **Adheed *et al.* [(2)]**.

Due to the importance of the topic, the study of PV at the levels of knowledge, attitude and practice is very useful. To find out more about the importance of documentation of adverse drug reactions it is enough to know that ADRs appear in 10% of outpatients, causing approximately 5-10% to be admitted to hospital **Aljadhey *et al.* [(3)].**

ADRs are regularly seen in the routine operations of pharmacies and hospitals, both privately and publicly held. The healthcare system faces financial difficulties as a result of the numerous evident morbidities and the deaths they produce. If pharmacists and other healthcare workers pay great attention to the information on the side effects of the medications given to patients, we can prevent ADRs. Understanding ADRs helps reduce the irrational usage of unsuitable medication. Consequently, there is a critical need to raise pharmacists' and prescribers' understanding of ADRs and medication monitoring **Omer *et al.* [(4)]**.

Healthcare providers need to be particularly aware of pharmacovigilance. Pharmacy and medicine students must get thorough instruction on how to recognize, avoid, and report ADRs. The healthcare providers' undergraduate training is the ideal period to increase their understanding of and aptitude for pharmacovigilance **Omer *et al.* [(5)]**.

The under-reporting of ADRs by them, however, is a concern in many nations, including the middle-east nations. Lack of awareness and expertise of methods to recognize and report ADRs may be used to explain this. The aim of the current study is to know the main barriers regarding the process of adverse drug reactions in the Middle East area.

PATIENTS AND METHODS

Search protocol

A manual search was conducted on the literature databases PubMed and Google Scholar in October 2022, using following key terms and sentences: Pharmacovigilance, adverse drug reaction, adverse drug reactions, barriers, marries to pharmacovigilance, Middle East.

Received: 21/7/2022
Accepted: 23/9/2022

Table 1 represents the inclusion and exclusion criteria for this search.

Table 1: Inclusion and exclusion criteria of the study.

Criteria	Inclusion criteria	Exclusion criteria
Language	English	All languages except English
Location of the study	Middle East countries	Which country is not located in the Middle East
Population	Physicians, pharmacists, dentists, pharmacy technicians and nurses.	Patients
Date of publication	2012-2022	Before 2012

Data analysis

The very important aspect that must be pointed out is that the focus was on extracting the main challenges or barriers for adverse drug reaction reporting from among other parts of the studies. In data analysis, reliance was placed on the author's opinion in diagnosing the main causes.

From the 102 papers screened manually, 26 studies from 12 countries were eligible to be included in the study. They were performed in the Egypt (4 studies), Saudi Arabia (4 studies), Iraq (5 studies), Bahrain (1 studies), Iran (2 studies), UAE (2 studies), Jordan (2 studies), Kuwait (2 studies), Qatar (1 studies), Palestine (1 studies), Yemen (1 studies) and Lebanon (1 study). The characteristics of included studies are described in **Table 2**.

Table 2: Features of included studies

Author/year	Location	Participants and sample size	Design	Data collection
Abdulrasool *et al.* [6]	Bahrain	Pharmacists, nurses and physicians (140)	Descriptive cross-sectional	Descriptive cross-sectional online survey and telephone interview
Qassim *et al.* [7]	UAE	Pharmacists (223)	Cross-sectional study using multistage sampling method, convenience and also use of random sampling	Interview questionnaire
Nashwa *et al.* [8]	Egypt	Physicians (both medical and dental) (211)	Cross-sectional survey	Self-administered questionnaire
ELkhwsky *et al.* [9]	Egypt	Pharmacists & physicians (547)	Cross-sectional survey	Self-administered questionnaire
Alharbi *et al.* [10]	Saudi Arabia	Pharmacists (130)	Cross-sectional survey	Self-administered questionnaire
Sathvik *et al.* [11]	UAE	Pharmacist and physicians (125)	Prospective cross-sectional study	Self-administered knowledge, attitude & belief (KAB) questionnaire
Al-Worafi *et al.* [12]	Yemen	Pharmacists & pharmacy technicians (179)	Cross-sectional survey	Validated and pilot-tested questionnaire
Alshabi *et al.* [13]	Saudi Arabia	Pharmacists, physicians, & academicians (27)	Qualitative study of 4 focus group discussions	Four focus group discussions
Alsaleh *et al.* [14]	Kuwait	Physicians (550)	Cross-sectional survey	Paper-based 25-item questionnaire
Wilbur [15]	Qatar	Pharmacists (116)	Cross-sectional survey	27-item questionnaire
Hajj *et al.* [16]	Lebanon (1857)	Community pharmacists	cross-sectional descriptive study	Self-administered KAP questionnaire
Khdour *et al.* [17]	Palestine	Pharmacists (270)	Cross-sectional study	Face to face questionnaire
Bahlol *et al.* [18]	Egypt	Community pharmacists (923)	Cross-sectional study	Self-administered questionnaire
Hussain *et al.* [19]	Iraq	Physicians, dentists & pharmacists (485)	quantitative cross-sectional study design	Self-administered KAP questionnaire
Alnawaiseh [20]	Jordan	Pharmacists (238)	Cross-sectional study	Interview based questionnaire
Al Rabayah *et al.* [21]	Jordan	Pharmacists, clinical pharmacist, physicians & nurses (306)	Cross-sectional study	Self-administered questionnaire
El-sayed [22]	Egypt	Pharmacists (190)	Cross-sectional study	Self-administered questionnaire
Payam *et al.* [23]	Iran	General Practitioners (333)	Cross-sectional study	Semi-structured questionnaire
AlShammari [24]	Saudi Arabia	Physicians, pharmacists & nurses (336)	Cross-sectional study	Self-administered questionnaire
Salih *et al.* [25]	Iraq	Pharmacists (176)	Cross-sectional survey	Self-administered questionnaire
Mirbaha *et al.* [26]	Iran	Nurses & Pharmacists (34)	Qualitative study of three focus groups discussions	Group discussions
Alsaleh *et al.* [27]	Kuwait	Pharmacists (342)	Cross-sectional study	Self-administered questionnaire
Mohammed *et al.* [28]	Iraq	Pharmacists (150)	Cross-sectional descriptive survey	Self-administered questionnaire
Khalid [29]	Iraq	Pharmacists (132)	Cross-sectional analytical study	Self-administered, validated questionnaire

Ethical approval:
This study received Ethical Approval from the Research and Publication Committee in Basrah region.

RESULTS

The main barriers for adverse drug reaction reporting have been shown in (**Table 3**).

Table 3: Main barriers for adverse drug reaction reporting

Author (year), country	Main barrier(s)
Abdulrasool *et al.* [6]	There is no determined reporting form, in other words, the absence of a special center for official Pharmacovigilance within the country.
Qassim *et al.* [7]	Lack of proper knowledge and weakness in the practice to complete the process of documenting side effects.
Nashwa *et al.* [8]	The majority of participants do not know how to report or document the ADRs. Another main barrier was that they not being sure if this is ADRs or not
ELkhwsky *et al.* [9]	Not having enough time (71%) and uncertainty in perception if this is ADRs or not (48%).
Alharbi *et al.* [10]	Weakness in pharmacovigilance training (46.6%).
Sathvik *et al.* [11]	Not knowing accurately who is responsible for ADRs reporting as well as how to report.
Al-Worafi *et al.* [12]	Difficulty to decide if patient has been harmed. Believing that reporting the ADRs give impression that they ignorant concerning ADRSs. Believing that the all serious ADRs no need to be registered because they are detected formerly.
Alshabi *et al.* [13]	Absence of professional environment to study ADR. No adequate knowledge related to pharmacotherapy and clinical pharmacy.
Alsaleh *et al.* [14]	No adequate knowledge about method and mechanism of reporting (about 76.35%).
Wilbur [15]	Difficulty to detection a potential ADR. Problem in mechanism of accessing to reporting form.
Hajj *et al.* [16]	Inadequate knowledge for reporting (23.6%). Problem in correctly distinguish and detection of ADR (23.2%).
Khdour *et al.* [17]	No adequate information provided by the patient (76.7%). Inadequate knowledge for reporting (266.7%).
Bahlol *et al.* [18]	Lack of understanding of the official procedure. Refusing to accept responsibility.
Hussain *et al.* [19]	Inadequate knowledge regarding ADRs. Absence of reporting form when there is need.
Alnawaiseh [20]	Low of knowledge to how report (72.1%). Low clinical knowledge leading to difficulty in deciding that if there is an ADR or not (72%). There is no enough time to report (70.9%). Did not know about presence of national ADR reporting system (70.8%). Reporting ADRs will produce extra work (70.6%). Unavailability of reporting form when needed (69.8%).
Al Rabayah *et al.* [21]	Lack in training and rules regarding the reporting (37.5%).
El-sayed [22]	Unsure if the reaction caused by ADRs (25%). ADRs were already well-known (15.5%). Forget to report the ADR (14.5%).
Payam *et al.* [23]	Lack of knowledge about the steps of the reporting of ADRs (53%).
AlShammari [24]	Uncertainly about the report that could be incorrect (46%). Lack of time (44%).
Salih *et al.* [25]	Lack of knowledge about the steps of the reporting of ADRs (33.3%). Unavailability of forms specialized for the reporting (71.6%) Lack of knowledge to which place the reports should be sent (71.6%).
Mirbaha *et al.* [26]	Lack of time and teamwork. Lack of assistance from the management team of the hospitals and also the colleagues. No knowledge of what must be reported.
Alsaleh *et al.* [27]	No communication by healthcare providers and patients. No time and management. Lack of knowledge of staff and patients.
Mohammed *et al.* [28]	The workplace does not encourage the healthcare provider for reporting (60%). No enough time (48%). Fear from legal problem (38%).
Khalid [29]	Ignorance of reporting locations and procedures (68.1%).

DISCUSSION

There is no doubt that many studies have been conducted [2,3] and are being conducted and will be conducted in the future to identify the reasons for the lack of adverse drug reaction reporting, but what is important is to focus on the main causes that appear in most studies of this kind. This study showed that the countries of the Middle East share many reasons and similarities in the roots of the lack of documentation.

Examining the results from these studies, it is no secret to anyone that the main obstacle in the way of adverse drug reaction reporting is the lack of knowledge and awareness about pharmacovigilance in general [1,4-11]. This lack of awareness includes how to fill the forms for pharmacovigilance, how to distinguish which adverse events should be recorded, the steps to document the ADR and to which side they will be sent. This problem, although its severity differs in some medical staff from others, but it exists in general with all of them.

In addition, given the results here, the subject of no enough time to reporting must be taken seriously, as six of the studies have shown it [9,12-16]. Depending on the nature of the work of each of the healthcare providers, so does the availability of time to reporting. Therefore, this topic should be discussed separately with each of them, whether a doctor or pharmacist and others.

Other barriers such as lack of motivation and professional environment for the practice of pharmacovigilance are related to the nature of the management of health authorities in each country.

CONCLUSIONS

What these 26 studies want to say is that the most important reason for the underreporting is no or little knowledge and awareness about pharmacovigilance practice and on the other hand the lack of mechanisms that facilitate documentation in terms of sufficient time, motivations or the environment as a whole.

DECLARATIONS

- **Consent for publication:** I can attest that all writers agree to submit the work.
- **Availability of data and material:** Available
- **Competing of interest:** None
- **Funding:** No fund
- **Conflict of interest:** No conflicts of interest are disclosed by the authors about the articles of this essay

REFERENCES

1. **Edwards I, Aronson J (2000):** Adverse drug reactions: definitions, diagnosis, and management. Lancet, 356:1255-59.
2. **Adheed K, Haydar F, Ghassan S *et al.* (2017):** Knowledge, Attitude and Practice towards Pharmacovigilance and Adverse Drug Reaction Reporting among Pharmacy Students in Basra University, Iraq. Int. J. Pharm. Sci. Rev. Res., 46(2):15; 83-87.
3. **Aljadhey H, Mahmoud M, Alshammari T *et al.* (2015):** A qualitative exploration of the major challenges facing pharmacovigilance in Saudi Arabia. Saudi Med J., 36(9):1097-102.
4. **Omer A , Naza S , Bnar S *et al.* (2017):** Adverse Drug Reactions (ADR's) Reporting Barriers and Attitude among Pharmacists in Erbil, Kurdistan Region – Iraq. J Basic Clin Pharm., 8: S061-4.
5. **Omer B , Ramadan E , Shazia J *et al.* (2013**): New Pharmacovigilance Course at the International Islamic University Malaysia-IIUM. Am J Pharm Educ., 77 (5): 1.
6. **Abdulrasool Z (2022):** The development of a pharmacovigilance system in Bahrain. Saudi Pharmaceutical Journal, 30(6): 825-41.
7. **Qassim S, Metwaly Z, Shamsain M , al Hariri Y *et al.* (2014**): Reporting Adverse Drug Reactions: Evaluation of Knowledge, Attitude and Practice among Community Pharmacists in UAE. Journal of Pharmacy, 4: 17-23.
8. **Nashwa N , Kamal M , Emad G , Eman M *et al.* (2014):** Adverse Drug Reactions Reporting, Knowledge, Attitude and Practice of Physicians towards it in El Minia University Hospitals. International Public Health Forum, 1(4): 13-7.
9. **ELkhwsky F , el Sayed I , Yassine M , Abdelmonem S , Salama M *et al.* (2021**): Healthcare professionals' knowledge and practice of and attitudes towards pharmacovigilance in Alexandria, Egypt: a cross-sectional survey. Drugs and Therapy Perspectives, 37(3): 124-36.
10. **Alharbi F , Bahnassi A , Alonazie W *et al.* (2016):** Attitude, knowledge and experience of hospital pharmacists with pharmacovigilance in a region in Saudi Arabia: A cross-sectional study. Tropical Journal of Pharmaceutical Research, 15(8): 1773-9.
11. **Sathvik S , Osama M , Abo-Aldan E , Soliman N *et al.* (2014):** Adverse drug reaction monitoring and reporting: knowledge, attitude and belief of physicians & pharmacists of Ras Al Khaimah, United Arab Emirates (UAE). Int J Pharm Sci Res., 5(2): 368.
12. **Al-Worafi M , Kassab W , Alseragi M , Almutairi S , Ahmed A , Ming C *et al.* (2017):** Pharmacovigilance and adverse drug reaction reporting: A perspective of community pharmacists and pharmacy technicians in Sana'a, Yemen. Ther Clin Risk Manag., 13: 1175-81.
13. **Alshabi M , Shaikh K , Shaikh A , Alkahtani A , Aljadaan A *et al.* (2022**): Knowledge, attitude and practice of hospital pharmacists towards pharmacovigilance and adverse drug reaction reporting in Najran, Saudi Arabia. Saudi Pharmaceutical Journal, 30(7): 1018-26.
14. **Alsaleh M , Lemay J , al Dhafeeri R , AlAjmi S , Abahussain A , Bayoud T *et al.* (2017):** Adverse drug reaction reporting among physicians working in private and government hospitals in Kuwait. Saudi Pharmaceutical Journal, 25(8): 1184-93.
15. **Wilbur K (2012):** PHP22 Pharmacovigilance in Qatar – a Pharmacist Survey. Value in Health, 15(7): A292.
16. **Hajj A , Hallit S , Ramia E , Salameh P *et al.* (2018**): Medication safety knowledge, attitudes and practices among community pharmacists in Lebanon. Curr Med Res Opinion, 34(1): 149-56.

17. **Khdour M , Yaghmour N , Hallak H , Dweib M , Al-Shahed Q , Jarab A *et al.* (2016):** Pharmacovigilance and Adverse Drug Reactions Reporting Process in West-Bank, Palestine. Palestinian Medical and Pharmaceutical Journal, 1(12): 122-9.
18. **Bahlol M , Bushell M , Khojah J , Dewey S *et al.* (2022):** Spontaneous adverse drug reaction reporting by community pharmacists: preparedness and barriers. Saudi Pharmaceutical Journal, 30(7): 2-9.
19. **Hussain A , Abbas N , Habeeb A , Abd-Ali K , Abdulrahman S *et al.* (2019**): Healthcare personnel's experience of reporting adverse drug reactions in Baghdad city: cross-sectional study. International Journal of Clinical Pharmacy, 41(5): 7-13.
20. **Alnawaiseh A , AL-Oroud Y (2022):** Knowledge, Attitude and Practices of Pharmacovigilance and Adverse Drug Reaction Reporting Among Pharmacists Working at Alkarak Governorate, Jordan. Biomedical and Pharmacology Journal, 15(2): 967-78.
21. **Al Rabayah A , Hanoun E , al Rumman R *et al.* (2019):** Assessing knowledge, attitude, and practices of health-care providers toward pharmacovigilance and adverse drug reaction reporting at a comprehensive cancer center in Jordan. Perspect Clin Res., 10(3): 115.
22. **El-sayed A , Abdel-Aty M (2018):** Evaluation of Knowledge, Attitude and Practices of Adverse Drug Reaction Reporting Among Hospital Pharmacists-Mansoura, Egypt, 2016-Cross Sectional Survey. Iproceedings, 4(1): 10610.
23. **Peymani P , Tabrizi R , Afifi S , Namazi S , Heydari T , Shirazi K *et al.* (2016):** Knowledge, attitude and practice of General Practitioners towards adverse drug reaction reporting in South of Iran, Shiraz (Pharmacoepidemiology report). International Journal of Risk and Safety in Medicine, 28(1): 25-31.
24. **AlShammari M , Almoslem J (2018):** Knowledge, attitudes & practices of healthcare professionals in hospitals towards the reporting of adverse drug reactions in Saudi Arabia: A multi-centre cross sectional study. Saudi Pharmaceutical Journal, 26(7): 925-31.
25. **Salih M , Abd A , Kurmanji J , Al-Lela Q *et al.* (2016):** Assessment of community pharmacists concerning pharmacovigilance in Iraq. Arch Pharm Pract., 7(4): 136.
26. **Mirbaha F , Shalviri G , Yazdizadeh B , Gholami K , Majdzadeh R *et al.* (2015):** Perceived barriers to reporting adverse drug events in hospitals: A qualitative study using theoretical domains framework approach. Implementation Science, 10: 110.
27. **Alsaleh M , Alzaid W , Abahussain A , Bayoud T *et al,* (2017**): Lemay J. Knowledge, attitude and practices of pharmacovigilance and adverse drug reaction reporting among pharmacists working in secondary and tertiary governmental hospitals in Kuwait. Saudi Pharmaceutical Journal, 25(6): 830-7.
28. **Mohammed I , Al-Razaq A (2017):** Knowledge and attitude of Iraqi pharmacists in Baghdad community toward adverse drug reactions monitoring. Asian Journal of Pharmaceutical and Clinical Research, 10(4): 219-22.
29. **Khalid A (2017):** Pharmacists' knowledge, attitude and practice about adverse drug reaction in Basra/Iraq. Int J Pharm Sci Res., 8(5): 1000-6.