Khalij Libya Journal of Dental and Medical Research. 2025;9(2):236-242
https://doi.org/10.47705/kjdmr.259215
eISSN:2708-888X

Original article

Evaluation of Pharmacovigilance Awareness Among Healthcare Providers and Patients: A Field Study

Wadiaa Benamer[1], Mustafa Targhi[1]*, Marwa Farhat, Safa Mosa

Department of Pharmaceutics, Faculty of Pharmacy, University of Tripoli, Tripoli, Libya
Corresponding Email. *m.targhi@uot.edu.ly*

Abstract
People use medicines at some point in their lives, so they need to understand what they are taking and the risks involved. With about over half a million medicinal product groups on the worldwide market, there's an almost infinite number of ways in which harm can arise from treatments themselves or from interactions between them, as well as, from dietary, environmental and gastric factors in addition, poor quality and fake medicines are also constant treats in many parts of the world, however, using of medicinal products have benefit and risk effects and, due to the many repeated mistakes and disasters that are associated with drugs' use and related products led the need of pharmacovigilance follow up. Pharmacovigilance (PV) supports safe and appropriate uses of drugs after marketing and use by a population. The spontaneous reporting system of Adverse Drug Reaction (ADR) is an essential component of pharmacovigilance; however, significant underreporting of ADR remains a major problem in developing countries. Knowledge of PV could form the basis for interventions aimed at improving reporting rates and consequently decreasing ADRs. This cross-sectional descriptive study was carried out to gain knowledge on how familiar health care providers and the relevant administration of the Ministry of Health are with the concept of pharmacovigilance. The study involved distributing a questionnaire form and interviews of 205 randomly selected persons (60 physicians, 75 pharmacists, 30 nurses, and 40 patients). The study showed significant number of health care providers have incomplete information on the concept of PV and how it is integrated into health care system, much less its purposes and the necessity to report ADRs during professional practice, in contrast, the pharmacists in general have much more information and awareness on PV, particularly those working with Ministry of Health in the Pharmacy and Medical Equipment Administration. Concerning the patients, unfortunately, neither the physicians nor the pharmacists were keen enough to advise their patients on how to differentiate between the expected side effects and the unexpected ADRs.
Keywords: *Pharmacovigilance, Pharmacist, Adverse Drug Reaction, Medicine Safety.*

Received*: 26/07/25*
Accepted*: 25/09/25*
Published*: 04/10/25*

Introduction

The use of medicines is an important aspect of many Public health programs (PHPs) that are designed to improve the health of a target population. Also, medicines are important not only because of their capacity to treat and prevent disease and to support PHPs, but also because the confidence of the public health policies of most countries is correlated linked to their confidence in the availability of medicines that are safe and effective [1]. Due to a lack of care and caution at the pre-clinical and clinical testing stages, there would be no guarantee for absolute safety when a drug is marketed and prescribed to large populations. This is because clinical trials involve several thousand patients at most, so less common side effects and ADRs were often unknown at the time a drug entered the market [2]. Another important drawback of clinical trials is that they can only report adverse reactions that occur within the finite duration of the trial because efficacy and safety of a new drug are generally determined on a few thousand carefully selected and followed-up trial subjects and patients according to strictly defined criteria. For this reason, only very frequent adverse reactions and mainly those depending on the drug's pharmacological properties can be observed during its clinical development [3].

Despite all the advantages of pharmacotherapy, adverse reactions are a recognized hazard of drug therapy. ADRs are any noxious, unintended, and undesired effects of a drug that occur at doses used for prevention, diagnosis, or treatment. They are unwanted or harmful reactions that occur after the administration of a medication or a combination of medications and are suspected to be related to the medication. The reaction may be a known side effect of the drug, or it may be a new, previously unrecognized ADR [4]. Even when medications are properly prescribed, issues like ADRs and poor medication adherence can significantly impact treatment outcomes [5].

Pharmacovigilance (PV), the science of monitoring and ensuring the safety of pharmaceutical products post-market, stands as a vital cornerstone in the realm of public health and medicine [6]. In other terms, (PV), as defined by the WHO (2002), is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems [7]. It encompasses the diligent surveillance of adverse events, the detection of potential safety signals, and the

evaluation of data from a wide array of sources, including scientific literature, regulatory reports, and patient feedback [8]. PV plays a crucial role in ensuring the safety of pharmaceutical products. It involves the systematic monitoring of adverse events and the detection of potential safety concerns related to drugs in any population [9].

The main objective of Pharmacovigilance is to regulate and ensure the safety & efficacy after the entry of the new drug molecule into the market for the treatment of diseases of the general population with different medical conditions [10]. Among the products covered by PV are herbal, medical, traditional, and complementary, vaccines and blood products, and biological and medical devices [1]. A country PV system should incorporate activities and resources at the facility, national, and international levels and foster collaboration among a wide range of partners and organizations that contribute to ensuring the safety [11].

Several methods have been used to quantify the frequency of ADRs. They include spontaneous ADR reporting, ecological studies and analyses of medical claims databases, prescription event monitoring, which collects all drug-related events that occur while patients are receiving selected monitored medications, and meta–analyses [12]. No single method can cover all the requirements or aspects for the efficient collection of ADRs data, and therefore a multiplicity of methods is needed [13]. Yet, as the volume of medical literature continues to grow, manual screening of this extensive corpus remains a fatiguing and time-consuming task. The need for efficient and accurate tools to assist PV efforts is substantial. Traditional computational methods like pattern matching, topic modeling, text mining, and classification etc., have been employed to review and filter the literature [14].

Spontaneous reporting system “A system whereby case reports of adverse drug events are voluntarily submitted by health professionals and pharmaceutical companies to the national PV center.” It is the most common method used in PV and the best one to generate signals on new or rare ADRs. This reporting scheme has contributed significantly to successful post-marketing drug safety surveillance and can be regarded as the cornerstone of pharmacovigilance [15]. This system is applied in the collection of post-marketing information on the safety of drugs and the identification of safety signals. Consequently, this system is used in the identification of signals of new, rare, and serious ADRs of drugs. This system makes it easier for physicians, patients, and pharmacists to report suspected ADRs to the PV center [16]. There are numerous limitations of the system scheme, including the poor quality of submitted reports, difficulty in calculating rates because of incomplete numerator (adverse events) data, along with inaccurate denominators (number of prescriptions), and limited ability to determine causality. However, the main limitation is under-reporting. The PV center collects all these reports and informs the stakeholders about the newly reported ADRs. By this method, we can monitor all drugs in the market throughout their lifecycles [17] [2]. This study was carried out to gain knowledge on how familiar the healthcare provider(s) are with the concept of PV and how it works, as well as to evaluate their awareness of its importance.

Methodology

This cross-sectional descriptive study was carried out by distributing 400 health care providers and patients. After exclusion of incomplete forms and interviews, a total of 205 questionnaire forms and interviews were selected, which included 60 physicians, 75 pharmacists (60 working in the selected health institutes and 15 administrative pharmacists in the Ministry of Health, M.O.H), 30 nurses, and 40 patients**.** The health institutes involved were Public Hospitals: Al Khadra Hospital, Tripoli Medical Center, Abu-Salem Accident and Trauma Hospital, National Heart Center, and Al Jalaa Maternity Hospital, in addition to Private Clinics: Al Masarra Clinic, Al Salam Clinic, Alshark Clinic, Al Najat Clinic, Al Diaa Clinic, and Al Razi Clinic.

The questions were designed to include information on the study participants, background questions on PV, ADRs, and the responsibility to report, national and international ADRs monitoring centers and PV/ADRs educational programs. In addition to questions specifically designed for patients.

Results

The background information on PV is presented in (Figure 1), where 53% of M.O.H pharmacists who participated in the study define the term PV correctly, 42% of the private pharmacists who participated in the study define the term PV correctly, about 27 % of the physicians who participated in the study define the term PV correctly, however, only 6% of nurses were correct.

For the important purposes of PV, 20% of M.O.H pharmacists were correct, followed by 16% of the private pharmacists, and neither the physicians nor the nurses were correct. For the elements of PV, 100% of M.O.H pharmacists stated them correctly, then 25% of the private pharmacists, followed by 20% of the physicians, and only 7% of the nurses.

Khalij Libya Journal of Dental and Medical Research. 2025;9(2):236-242
https://doi.org/10.47705/kjdmr.259215
eISSN:2708-888X

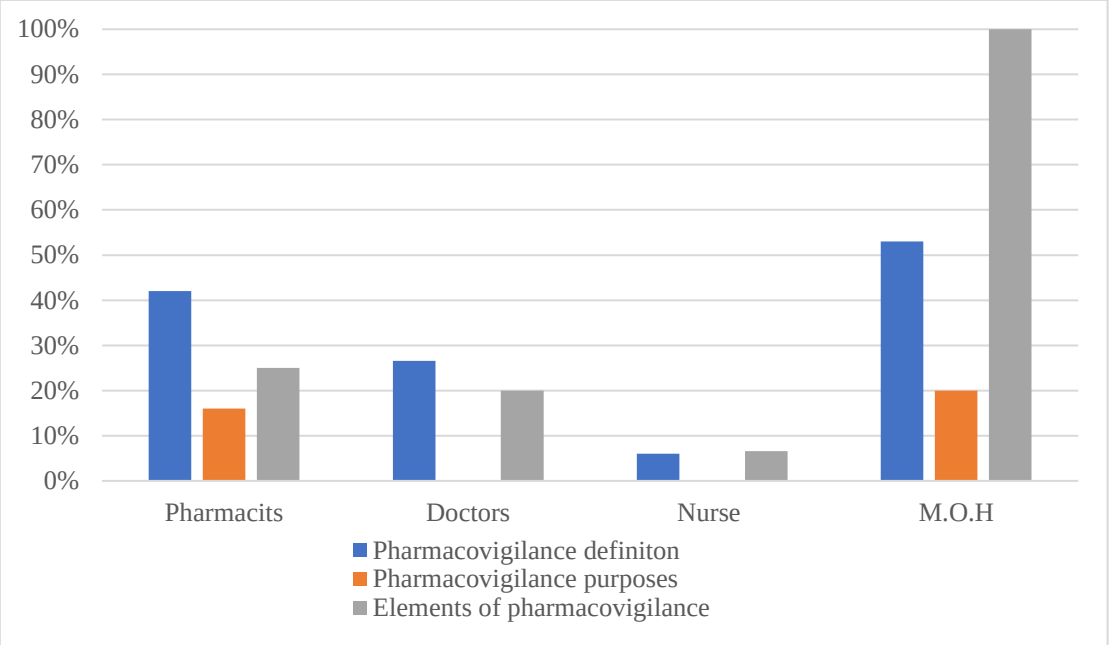

Figure 1. Background information on pharmacovigilance

The Knowledge on ADRs is presented in (Figure 2), from which 100% of both the community and the M.O.H pharmacists, in addition to 50% of the physicians and 38% of the nurses were knowledgeable on PV.,100% of the M.O.H. pharmacists said that, reporting ADRs is necessary, followed by 90% of both the private pharmacists and the physicians, however, only 38% of the nurses agreed with the necessity of reporting, furthermore, 80% of physicians, private pharmacists and M.O.H. pharmacists correctly identified the healthcare professional responsible for reporting ADRs, compared to 60% of nurses.

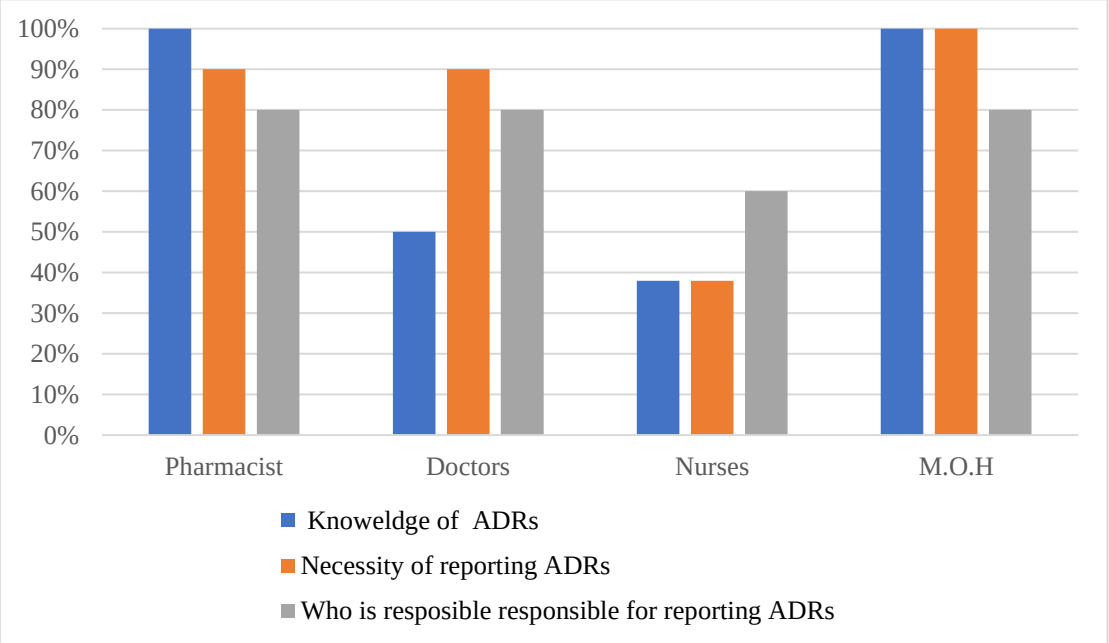

Figure 2. The need-to-know ADRs and the responsibility to report.

From (Figure 3), 100% of the M.O.H. pharmacists, 58% of the private pharmacists, 5% of the physicians and, none of the nurses knew the existence of a national PV program in Libya, in addition, all physicians and nurses stated that in their institute, there was no PV system or committee despite the presence of PV committee and office in the ministry of health. For the existence and location of the international ADRs monitoring center, 92% of the M.O.H. pharmacists, 25% of the private pharmacists, 20% of the physicians, and 5% of the nurses confirm the existence and location of the international center correctly.

Khalij Libya Journal of Dental and Medical Research. 2025;9(2):236-242
https://doi.org/10.47705/kjdmr.259215
eISSN:2708-888X

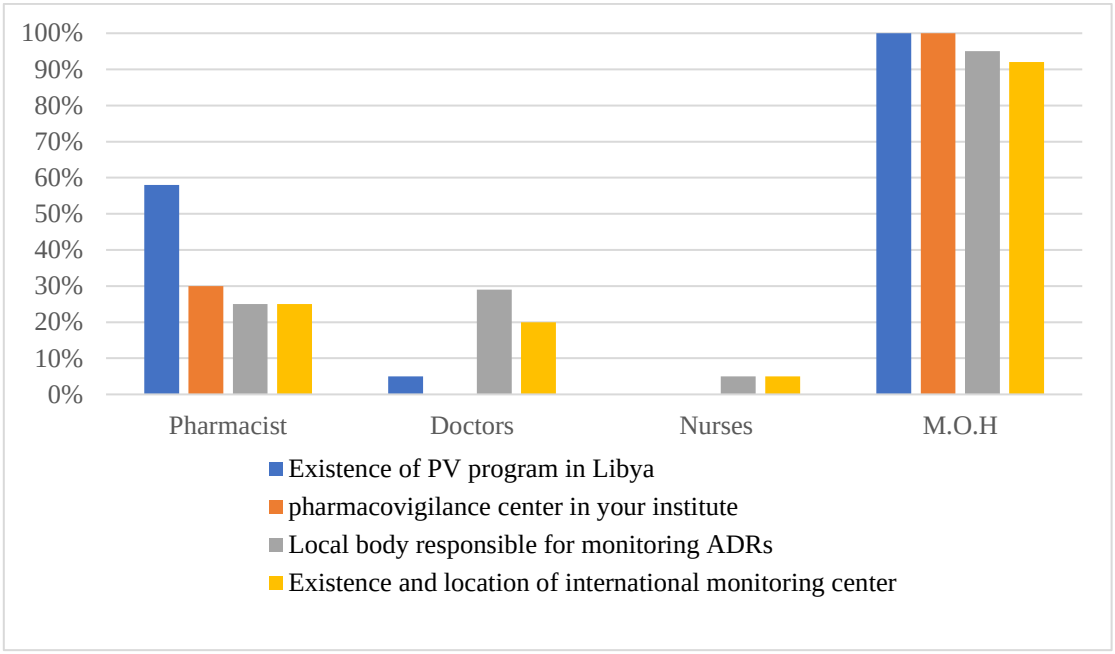

Figure 3. Existence and location of the national and international monitoring centers

Figure 4 demonstrates the answers of the study participants on several issues concerning PV and ADRs, for example, the idea of teaching PV to healthcare professionals, 100% of the M.O.H. pharmacists, 98% of the private pharmacists, 79% of the physicians, and 96% of the nurses agree to the idea, in addition, 100% of the M.O.H. pharmacists, 95 % of the pharmacists, 40% of the physicians and 8% of the nurses read article(s) on the prevention of ADRs and for reading article(s) on PV programs/systems, 33 % of the private pharmacists, 23% of the physicians, 20% of the M.O.H. pharmacists and 3% of the nurses said yes. Concerning the necessity for educational programs on PV and ADRs, 100% of the M.O.H. pharmacists, 98 % of the private pharmacists, 78% of the physicians, and 96% of the nurses agree to the idea.

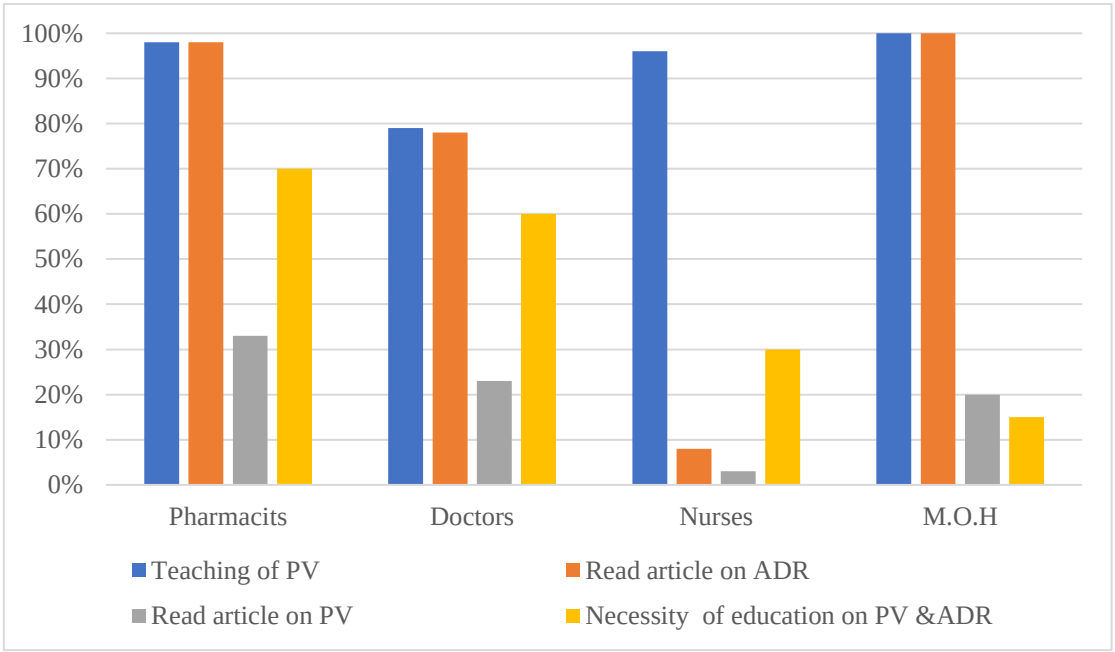

Figure 4. Education and knowledge on ADRs & Pharmacovigilance

(Figure 5), illustrates the experience of the participants with ADRs, from which 36% of the physicians, 41 % of the private pharmacists, 26% of M.O.H. pharmacists and 3% of the nurses have faced with ADRs in their patients, adding to that, 86 % of physicians, 93% of pharmacists, 0% of nurses and 99% of the M.O.H. pharmacists were aware of any recent banned drug (s) due to ADRs, however, none of either the physicians or nurses, 16% of the private pharmacists and 66% of the M.O.H. pharmacists have seen

Khalij Libya Journal of Dental and Medical Research. 2025;9(2):236-242
https://doi.org/10.47705/kjdmr.259215
eISSN:2708-888X

ADRS reporting form. Although reporting ADRs is important, the lack of a reporting center was the main barrier to mandating reporting of ADRs; however, 59% of the private pharmacists, 49% of the physicians, 28% of the nurses, and 100% of the M.O.H. pharmacists believed that reporting should be made mandatory.

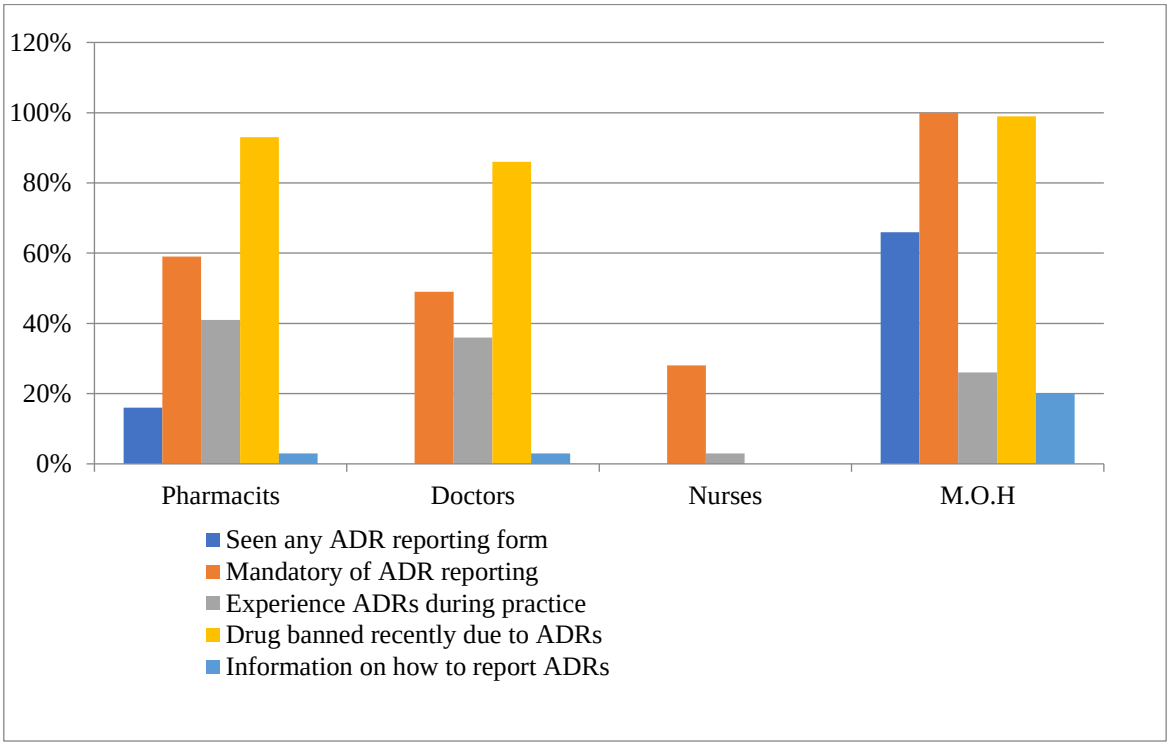

Figure 5. Personal experience and impressions

Concerning the patients' part of the study, because of a language barrier for most patients, the questions were translated and explained in arabic language. (Figure 6) summarizes the patients' answers to questions relevant to the physicians, from which 59% of the physicians withdraw their patients' attention to possible and expected side effects of the treatment, 58% asked their patients to report any side effects encountered, 55% warned their patients their patients about any unexpected side effects (ADRs), however, only 5% told their patients to immediately stop the treatment and return to them when any ADRs occurred.

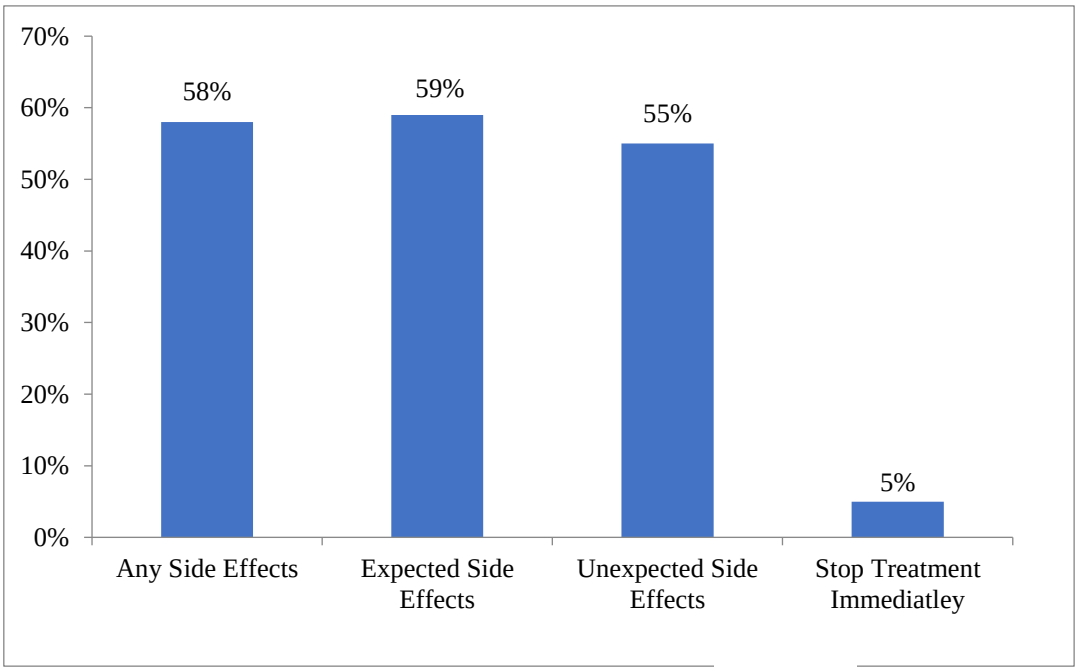

Figure 6. Patients' response to doctors' communication

Khalij Libya Journal of Dental and Medical Research. 2025;9(2):236-242
https://doi.org/10.47705/kjdmr.259215
eISSN:2708-888X

(Figure 7), illustrates the answers of questions by the patients relevant to pharmacists, where 57% of the pharmacists indicated to their patients the possible and expected side effects of the treatment, 59% warned them about the possible unexpected side effects (ADRs) and interestingly, 20% asked their patients to immediately stop the treatment and return to their pharmacists or physicians for consultation.

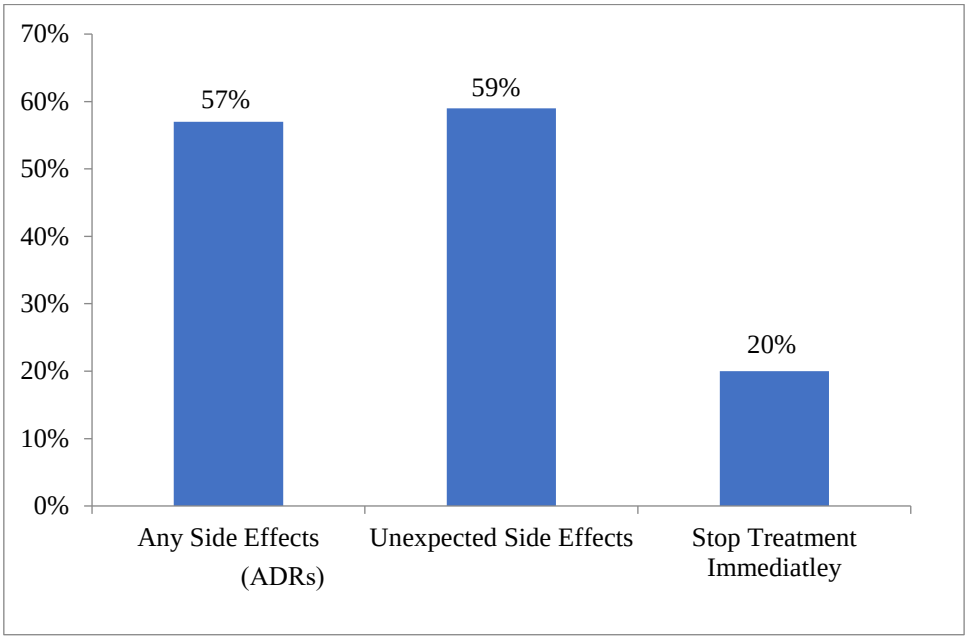

Figure7. Patients' response to pharmacists' communication

Discussion

Because the main goal of the study is to evaluate the extent of the knowledge on PV concept among healthcare professionals and patients, and whether all unwanted symptoms that appear after medication therapy were considered as side effects or as ADRs or events, the results showed that not all healthcare professionals sufficiently knew about PV and how to distinguish between side effect and ADRs or events and much less, keen to attend conferences, workshops or training programs inside or outside the country on PV. Moreover, when any strange, unanticipated symptom(s) appear after medication therapy, most physicians simply stop the medication. In contrast, the pharmacists in general have at least the basic knowledge, especially those in the pharmacy and medical equipment administration, to be more specific, those in the PV unit, thanks to the course curriculum of the Faculty of Pharmacy at the University of Tripoli.

Libyan nurses absolutely have no idea, while the foreign nationality nurses have a somewhat basic idea, this was because of the language barrier and the course curriculum taught to local nurses. It is interesting to note that 95% of the interviewed physicians and all the nurses were not aware of the existence of a local PV program in Libya, while about 58% of the interviewed private pharmacists were aware of the existence of a local PV program. The pharmacists have read articles on ADRs and PV more than the physicians and the nurses; again, this was because of the faculty of pharmacy course curriculum. After the PV concept and purposes were explained to them, most of these health professionals think it is necessary to teach and educate in detail PV to all healthcare professionals.

Concerning the patients, unfortunately, neither the physicians nor the pharmacists were keen enough to fully advise their patients on what to do in case of ADRs, much less to explain to them how to differentiate between expected side effects and ADRs. The main framework of the PV office within the M.O.H was to communicate with the Uppsala center to inquire about the banned and restricted medicines, then inform the relevant health establishments to stop dealing with such medicines.

Conclusion

Many healthcare professionals have very little or no idea what pharmacovigilance (PV) is about and its components or purposes. The findings emphasize the need for enhanced educational efforts, particularly targeting nursing staff & to a lesser extent, physicians, to ensure a comprehensive understanding & participation in ADR reporting across all healthcare. The health authority, in cooperation with the faculty of Pharmacy, must put more effort into educating health professionals and the public on PV's importance and purposes. The local PV program should improve itself, by association with various regional and international ADRs centers, especially the WHO through its affiliated Uppsala center. The Pharmacy &

https://doi.org/10.47705/kjdmr.259215
eISSN:*2708-888X*

medical equipment administration should set restricted rules for registering drugs to include thorough PV studies. The faculty should improve its curriculum to include details, rather than the basics of PV, including the international ADR monitoring centers. It is highly recommended that units of PV should be set in every major health care setting.

Conflict of interest

The authors declare that they have no conflicts of interest related to this article.

References

1. World Health Organization. The safety of medicines in public health programs: pharmacovigilance: an essential tool. Geneva: WHO; 2006.
2. Lučić MM, Milošević NP, Martić NB, Paut-Kusturica MM, Jovančević VM, Ubavić MB, et al. The role of a pharmacist in pharmacovigilance system. Hosp Pharmacol. 2018;5(3):715-27. doi: 10.5937/hpimj1803715L.
3. Sriram S, Ghasemi A, Ramasamy R, Devi M, Balasubramanian R, Ravi TK, et al. Prevalence of adverse drug reactions at a private tertiary care hospital in south India. J Res Med Sci. 2011;16(1):16-25.
4. Olsson S. The role of the WHO program on international drug monitoring in coordinating worldwide drug safety efforts. Drug Saf. 1998;19(1):1-10. doi: 10.2165/00002018-199819010-00001. PMID: 9673854.
5. Ben Zekri EMN, Rghebi NA, Elmzughi RF. Association between antiepileptic drug side effects and medication adherence among Libyan epilepsy patients. Mediterr J Pharm Pharm Sci. 2025;5(2):20-30. doi: 10.5281/zenodo.15118894.
6. Maqbool M, Dar MA, Rasool S, Bhat AU, Geer MI. Drug safety and pharmacovigilance: an overview. J Drug Deliv Ther. 2019;9(2):543-8.
7. World Health Organization. The importance of pharmacovigilance: safety monitoring of medicinal products. Geneva: WHO; 2002.
8. Böhm R, von Hehn L, Herdegen T, Klein HJ, Bruhn O, Petri H, et al. OpenVigil FDA - inspection of US American adverse drug events pharmacovigilance data and novel clinical applications. PLoS One. 2016;11(6):e0157753. doi: 10.1371/journal.pone.0157753.
9. Li D, Wu L, Zhang M, Shpyleva S, Lin YC, Huang HY, et al. Assessing the performance of large language models in literature screening for pharmacovigilance: a comparative study. Front Drug Saf Regul. 2024;4:1379260. doi: 10.3389/fdsfr.2024.1379260.
10. Sahu RK, Yadav R, Prasad P, Roy A, Chandrakar S. Adverse drug reactions monitoring: prospects and impending challenges for pharmacovigilance. In: Management of adverse drug reactions: a review. 2014. p. 1-9.
11. Elshafie S, Zaghloul I, Roberti AM. Pharmacovigilance in developing countries (part I): importance and challenges. Int J Clin Pharm. 2018;40(4):758-63.
12. Gibbons RD, Amatya AK, Brown CH, Hur K, Marcus SM, Bhaumik DK, et al. Post-approval drug safety surveillance. Annu Rev Public Health. 2010;31:419-37. doi: 10.1146/annurev.publhealth.012809.103649.
13. Fletcher AP. Spontaneous adverse drug reaction reporting vs event monitoring: a comparison. J R Soc Med. 1991;84(6):341-4.
14. Bugard T, Bittermann A. Reducing literature screening workload with machine learning. Z Psychol. 2023;231(1):3-15. doi: 10.1027/2151-2604/a000509.
15. Prajapati K, Desai M, Shah S, Panchal J, Kapadia J, Dikshit R. An analysis of serious adverse drug reactions at a tertiary care teaching hospital. Perspect Clin Res. 2016;7(4):181-6. doi: 10.4103/2229-3485.192044. PMID: 27843794.
16. Edwards A. The importance of pharmacovigilance. London: Royal College of Physicians; 2005.
17. World Health Organization. WHO pharmacovigilance indicators: a practical manual for the assessment of pharmacovigilance systems. Geneva: WHO; 2015.