

Original article

Knowledge, Attitude and Practice of Pharmacovigilance Among Libyan Pharmacists in Benghazi

Abdelhamid Senussi^{1*}, Azza Grew²

¹Department of Pharmacology, Faculty of Medicine, University of Benghazi, Libya

²Department of Family and Community Medicine, Faculty of Medicine, University of Benghazi, Libya.

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Corresponding Email. abdelhamid.senussi@uob.edu.ly

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ABSTRACT

Pharmacovigilance is meant to ensure patients' safety from adverse drug reaction (ADR). This study aims to assess knowledge, attitude and practice of pharmacovigilance and ADR reporting among pharmacists in Benghazi- Libya. A cross-sectional questionnaire-based study involving knowledge, attitude and practice of pharmacovigilance and it targeted 93 pharmacists at Benghazi medical center. The study showed that pharmacists' knowledge was 63%, and their attitude was positive. However, their practice was clearly poor. The present study illustrated that there is a need for immediate improvement of ADR monitoring and the importance of CME on pharmacovigilance programs.

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INTRODUCTION

The drug safety is a global issue and the assessment of drug toxicity is of a great concern to health authorities and patients' wellbeing worldwide, however the concept of pharmacovigilance is still lacking the required attention by healthcare providers specially in our country. According to the World Health Organization (WHO), pharmacovigilance is defined as "the science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine problem" [1]. Adverse drug reaction (ADR) is any adverse reaction to an unwanted and harmful drug effect at normal doses used for disease prevention, diagnosis, therapy, or modifying physiological function [2]. ADR is a serious problem leading to patients' morbidity and even mortality all over the world [3].

Safety monitoring of drugs is of great concern all over the world. Many unfortunate incidences of drugs' reactions made us think thoroughly of drug safety. Drug safety became a necessity after a series of mishaps of babies' malformation caused by thalidomide in late 1950s and patients' death after using general anesthetics [4].

Pharmacovigilance started more than 100 years ago although was not known as today and reporting the ADRs was the job of doctors, but nowadays it widens to include all healthcare professionals like nurses, pharmacists...etc. and in some countries even patients can report [5,6]. It was reported that up to 197,000 deaths are attributed to ADR in European countries and this picture could be much worse in developing countries [7].

The economic burden of ADR is a significant issue, and on average it costs about 9,500 USD for every ADR suffering patient. Therefore, periodic evaluation of healthcare professionals including pharmacists towards pharmacovigilance is of great importance to tackle the issue of ADR and ensures patients' safety [8]. In Egypt, a recent study showed that knowledge of pharmacovigilance is about 40% among physicians and pharmacists while the practice was 50% and the attitude was positive [9]. In Libya, a study was conducted in Tripoli among pharmacists showed that pharmacovigilance's knowledge about 40% and the attitude was 58% [10]. This study was conducted to assess the knowledge, attitude and practice of pharmacists in Benghazi Medical Center about ADR and pharmacovigilance.

METHODS

Study design

A cross-sectional study was conducted on 93 pharmacists working at Benghazi Medical Center in Benghazi-Libya. All participants must have bachelor degree of pharmacy to be eligible in this study and they willingly gave their verbal consent.

Data collection

A questionnaire was used to collect data which included; 28 questions based on previously published study by Koneru D. et al [11]. It has 6 questions about knowledge, 3 questions for practice and 19 questions for attitude towards pharmacovigilance. The study lasted from April to July 2024.

Data analysis

Data was analyzed using IBM SPSS V.21.

Ethical consideration

Ethical approval was obtained from the ethical committee in the Benghazi Medical Center.

RESULTS

The questionnaire was distributed on 110 pharmacists, but 93 only completed it (response rate=84.5%). In regards to the knowledge about presence of ADR reporting system in Libya and Benghazi; 38.7% and 23% recognized them respectively.

Concerning the factors that may be associated with ADR about 95% agreed that old people and young children are associated with ADR, while 98.86% said polypharmacy is most likely to be associated with ADR.

For patients in Intensive care unit (ICU) and patients with multiple comorbidities and their association with ADR, most of the participants about 97% agreed that they most likely to be linked to ADR, as shown in figure 1.

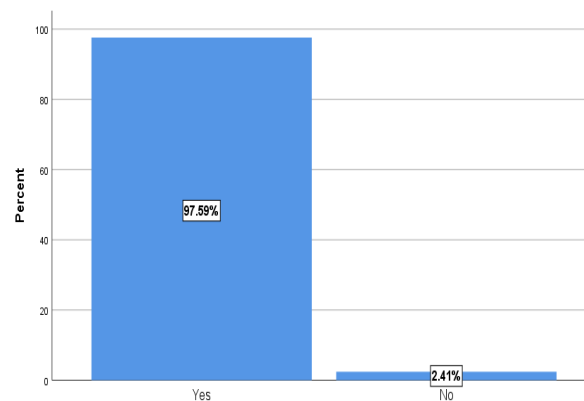


Figure 1. Distribution of pharmacists about their knowledge that patients in ICU and patients with multiple comorbidities are associated with ADR

For the essential information that should be included in ADR reporting the response, as shown in table 1. Majority of the pharmacists around 90% knew the basic information that should be included in ADR reporting.

Table 1. Knowledge of the pharmacists about the basic information in ADR report.

Essential information in ADR report	Yes (%)	No (%)
Patient's initials	84.34	15.66
Name of the reporter	88.89	11.11
Suspected medication	89.89	10.11
Start's date of the reaction	94.44	5.56
Outcome of the event	91.76	8.24

As shown in figure 2 below, around 50% of the pharmacists in this study did not know any drug that was removed from market because of safety reason.

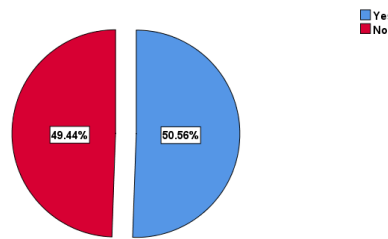


Figure 2. Distribution of pharmacists according to their knowledge about withdrawal of any drug from market because of safety reason

Table 2 showed that nearly equal proportions (18.39% & 18.52%) of the pharmacists in this study did not know that ADR reporting is required when it is caused by over-the-counter drugs & by topical agents respectively. Regarding, reporting ADR when it is caused by herbal medications, 23.53% of pharmacists knew about that.

Table 2. Knowledge of pharmacists about conditions needed to be reported.

Do you think ADR reporting is required in the following situations?	Yes (%)	No (%)
When it is caused by over-the-counter drugs?	81.61	18.39
When it is caused by topical agents?	81.48	18.52
When it is caused by herbal medication?	76.47	23.53

It was noticed that 82.5% of the pharmacists in this study, think that ADR reporting is not needed when they are not certain that a drug might have caused the reaction in the patients.

In regards to the assessment of attitude of the participants in this study about 95% agreed that ADR will add benefit to patients' care, 72.5% would suspect ADR even when drugs are given in normal doses, 69% agreed reporting seemingly insignificant ADR, 88% agreed to report all ADRs for new drug, 91% thought ADR reporting is the duty of healthcare professionals, 77% agreed seriousness of ADR and reaction to new drug would encourage them to report and less than 3/4 (71%) said unusual reaction push them to report ADR. Nearly 2/3 (65%) of the pharmacists in this study would report well-known events that occur with a drug.

About the factors that would prevent them to report ADR; fear of sending inappropriate form (41%), busy schedule to fill up the form (39%), no fees for reporting ADR (35%), and 20% said not sending one report would not affect patients' care. Concerning difficulty diagnosing ADR; 68% said it is difficult to diagnose ADR in clinical practice, and 72% said non-availability of the ADR forms at workplace prevents reporting. Regarding their attitude about reporting previously known ADR, 23% of the pharmacists said; it is not needed, 20% said pharmacovigilance department's forms are complex to use and 50% said reporting ADR must be done by pharmacists.

Table 3. Assessment of pharmacists' attitude.

Questions about attitude	Agree answers (%)
Do you agree that ADR reporting system will add benefit to patient's care?	94.6
Do you agree to suspect ADRs when drug is administered in normal dose?	72.5
Do you agree reporting of apparently insignificant ADRs is required?	69.2
Reporting all ADRs for a new drug is important	88
Reporting of ADR is a duty of health care professional (doctor, nurse, pharmacist)	91
Do you think seriousness of event pushes you to report ADR?	77
Do you think unusual reaction make you report ADR	71
Do you think reaction to a new drug encourages you to report ADR?	77.2
Do you think certainty that the reaction is an ADR, encourages you to report ADR?	77
Do you think well-recognized events that are known to occur with the drug encourage you report ADR?	65.2
fear of sending inappropriate forms, prevents you reporting ADR	40.6
Busy Schedule to fill the form, prevents you from reporting ADR	39.1
No payments for reporting ADR, prevent you report ADR	35.2

Not reporting one drug's ADR may not affect the patient's care	20.4
Difficult to diagnose ADR in clinical practice interferes with reporting ADR	68
Non-availability of reporting form at workplace, prevents reporting ADR	72
Do you think reporting previously known ADR is not required?	23
Do you think that forms of pharmacovigilance department for reporting ADR are complex to use?	20
Do you agree that reporting ADR events should be compulsory filled by pharmacist?	50

For the assessment of practice of pharmacovigilance of the pharmacists enrolled in the study, only about 12% had reported ADR. Only 9 out of 93 pharmacists reported ADR. Their distribution according to the drug class reported by pharmacists was as follows; two pharmacists reported ADR due to antifungal drugs, also two pharmacists reported ADR due to antihyperlipidemic drugs and five pharmacists reported the following classes; anticancer, antimalarial, hypertension drug, diabetes mellitus drug, and antibiotic.

Table 4. Distribution of ADR reporting by pharmacists according to drug class

Drug class	Number of reporters
Antifungal	2
Antihyperlipidemic	2
Anticancer	1
Antimalarial	1
Hypertension drug	1
Diabetes mellitus drug	1
Antibiotic drug	1

DISCUSSION

This study showed that the knowledge of pharmacists working in Benghazi Medical Center was 63% compared to 42% in Ethiopia and 45% in Sudan [12,13]. The obtained results exhibited that 37% of pharmacists knew about the existence of national pharmacovigilance department- ministry of health-Libya, in comparison to a study by Atia A. et al. in Tripoli reported that the knowledge of pharmacists about the department is 14.7% [10]. Similar studies had shown that poor knowledge was recorded among healthcare professionals about the existence of regional or hospital pharmacovigilance department for example in turkey, a recent study showed only 51% knew about pharmacovigilance in their hospital while in Jordan; a study conducted on community pharmacists showed that only 6.7% recognized the national pharmacovigilance system [8,17].

Regarding the assessment of attitude, our study showed that a positive attitude towards pharmacovigilance which also reported by other studies; Khaz Z. et al. in Adana province in Turkey (2023), Atia et al. in Tripoli Libya (2021), in Nigeria (2021) and also was reported in Pakistan in 2018 [8,10,14,15].

Concerning practice; there was poor practice due to lack of proper education and training resources of pharmacovigilance, as a result only 12% of the pharmacists in the current study reported ADR in comparison to a study conducted in Saudi Arabia that found 21.9% had reported ADR [16].

CONCLUSION

The ADR and pharmacovigilance principles needed to be enforced in every hospital to ensure good patients' healthcare. Periodic assessment of pharmacovigilance activities for healthcare professionals is of great importance to provide competent pharmacists. The overall knowledge of pharmacists in this study was 63% towards pharmacovigilance and their attitude was positive, however there was a clear deficit in their practice which could be attributed to lack of training and their reluctance for attending such activities. This study showed the need to establish ADR reporting system in every hospital and to apply mandatory training for healthcare professionals including pharmacists. This study the first to be held in Benghazi and only 93 pharmacists were included, so further studies with larger samples including other healthcare professionals needed to be carried out.

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Conflicts of Interest. Nil.

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معرفة وتوجهات وممارسة اليقظة الدوائية لدى الصيادلة في بنغازي

عبد الحميد السنوسي، عزة قريو

قسم علم الأدوية، كلية الطب، جامعة بنغازي، ليبيا
قسم طب الأسرة والمجتمع، كلية الطب، جامعة بنغازي، ليبيا

المستخلص

اليقظة الدوائية تعنى بتأكيد سلامة المرضى من الأعراض الجانبية للأدوية وهذه الدراسة جاءت لقياس مدى معرفة وتوجهات وممارسات الصيادلة في بنغازي بمفهوم اليقظة الدوائية. استخدمت دراسة مقطعية باستبيان وشملت 93 صيدلي في مركز بنغازي الطبي. أوضحت الدراسة ان معرفة الصيادلة باليقظة الدوائية 63% وتوجهاتهم إيجابية ولكن هناك قصور واضح بما يخص ممارستهم. أوضحت هذه الدراسة الحاجة العاجلة لتحسين مراقبة الأعراض الجانبية للأدوية والحاجة الى التعليم الطبي المستمر بما يخص برنامج اليقظة الدوائية. الكلمات الدالة. الآثار الجانبية للأدوية، اليقظة الدوائية، الصيادلة، بنغازي.