西 南 交 通 大 学 学 报

第 56 卷 第 1 期
2021 年 2 月

JOURNAL OF SOUTHWEST JIAOTONG UNIVERSITY

Vol. 56 No. 1
Feb. 2021

ISSN: 0258-2724 **DOI：10.35741/issn.0258-2724.56.1.13**

Research article

Education

A QUESTIONNAIRE STUDY ON THE KNOWLEDGE, ATTITUDE, AND PRACTICE OF PHARMACOVIGILANCE AMONG PRACTICING HEALTHCARE PROFESSIONALS OF THE TEACHING HOSPITAL IN SEBHA, LIBYA

利比亚塞巴州教学医院实践医疗保健专业人员之间的药物警戒知识，态度和实践的问卷调查研究

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Received: November 8, 2020 ▪ Review: December 5, 2020 ▪ Accepted: January 7, 2021

Abstract

Pharmacovigilance is assessing whether the benefits of a drug outweigh the risks, and it does not stop when a drug is certified. Pharmacovigilance involves ongoing monitoring of drugs to ensure they remain safe for use, especially since previously undetected adverse events can occur at any time. However, this concept is still new to some healthcare professionals. Currently, significant attention has been drawn to pharmacovigilance in Arab countries due to the development of new regulations. The present cross-sectional, qualitative study used a questionnaire to assess knowledge of, attitudes towards, and practice (KAP) of pharmacovigilance among healthcare professionals (doctors, dentists and pharmacists) working in Sebha Medical Centre and Medical Facilities. The findings revealed a difference between healthcare professionals' explicit and tacit knowledge. The questions about attitudes identified respondents' affective behavior, while the questions about the practice were found the lack of practice of pharmacovigilance, mainly due to non-availability of suspected ADR reporting form, not considering reporting as necessary, fear of consequences, and lack of awareness among healthcare professionals. This study highlights healthcare professionals' limited knowledge of pharmacovigilance. Drug regulatory bodies and health authorities should implement educational interventions and a practical training program to strengthen drug safety and pharmacovigilance in Libya.

Keywords: adverse drug reaction, healthcare professional, sustainability, pharmacovigilance

摘要 药物警戒性正在评估药物的益处是否大于风险，并且在药物获得认证后也不会停止。药物警戒性涉及对药物的持续监控，以确保其使用安全，尤其是因为以前未发现的不良事件可能随时发生。但是，对于某些医疗保健专业人员而言，此概念仍然是新概念。当前，由于新法规的制定，阿拉伯国家的药物警戒已经引起了极大关注。本横断面定性研究使用问卷调查来评估在塞卜哈医疗中心和医疗机构工作的医疗保健专业人员（医生，牙医和药剂师）对药物警戒的了解，态度和实践（KAP）。调查结果表明，医护人员的显性知识和隐性知识之间存在差异。有关态度的问题确定了受访者的情感行为，而有关行为的问题则发现缺乏药物警戒的实践，这主要是由于无法获得可疑的 ADR 报告表，未考虑必要的报告，担心后果，以及缺乏医护人员之间的意识。这项研究强调了医疗保健专业人员对药物警戒性的有限了解。药品监管机构和卫生当局应实施教育干预措施和实践培训计划，以加强利比亚的药品安全和药物警戒。

关键词: 药物不良反应，医疗保健专业人员，可持续性，药物警戒

I. INTRODUCTION

Adverse drug reactions (ADRs) may have caused over 100,000 deaths in 1994 in the United States [1]. ADRs are a significant cause of morbidity and place a substantial burden on limited healthcare resources [2], [17]. In Western countries, it has been estimated that serious ADRs occur in 6.7% of hospitalized patients and are responsible for approximately 5–9% of inpatient costs [3], [4]. A study conducted in England found that between 1999 and 2008, ADRs were associated with 0.9% of all emergency hospital admissions and 26,399 deaths [5]. Two meta-analyses of observational studies showed a proportion of preventable ADR-related hospital admissions ranging between 28.9% and 52.0% [6]. Reporting the side effects of medicines is an important, effective way to improve drug safety and ensure proper delivery to patients worldwide. However, little is known about pharmacovigilance (PV) and its role in increasing drug safety [7]. Little research has addressed healthcare professionals' (HCPs) reporting of drug side effects and the effectiveness of such reports; in addition, few studies have examined the factors that prevent effective reporting or what is done with reported data [7]. All of these issues fall under the topic of pharmacokinetics ADRs primarily due to increased chronic disease, and age-related physiological changes affecting the pharmacokinetics of drugs. All HCPs have a role to play in effective PV. In order to anticipate, identify, record and report drug side effects, community pharmacists must first have a thorough understanding of the drugs themselves; this will facilitate the identification of side effects. Therefore, knowledge and the minimization and prevention of harmful drug side effects are important objectives of successful pharmacotherapy (treatment of a disorder or disease with a medication). Pharmacists in both community and institutional settings frequently encounter reports of adverse events [8].

II. RESEARCH OBJECTIVES

This study was conducted to identify and assess the KAP of PV among HCPs working at Sabha Medical Center and Medical Facilities.

III. LITERATURE REVIEW

Adverse drug reactions (ADRs) are an important public health problem and a major cause of morbidity and mortality [9]. However, in several countries, no studies on this issue have been conducted recently. An ADR is defined as a noxious, unintended injury arising from drug-related causes [10]. Growing evidence of the increasing frequency and severity of ADRs, which are associated with negative impacts on the patient's health status, also reveals that ADRs place a significant burden on healthcare facilities. ADRs can increase the length of hospital stays and may need to be treated with additional tests, procedures, and drug therapies [11]. ADRs account for 5–10% of all hospital admissions [12]; findings vary depending on the individual study design, the study population and the definition of ADR used in a study [12], [13]. Furthermore, differences in available medicines and medical practice could result in different ADR frequencies found by epidemiological studies in European and U.S. hospitals [14]. A survey ordered by European Commission estimated that 5% of hospital admissions in Europe are due to ADRs, 5% of all hospitalized patients experience an ADR during a hospital stay, and ADRs are the fifth most common cause

of death in hospital settings [15]. Moreover, 197,000 deaths per year in the EU are caused by ADRs; the total cost of ADRs to society in the EU was €79 billion in 2008 [16]. A landmark meta-analysis by Lazarou et al. [3] found that ADRs were the fourth to sixth most common cause of death in the United States, following ischemic cardiopathy, cancer, and stroke. Similarly, Davies et al. [18] found that ADRs increased the risk of mortality.

IV. Materials and Methods

The present cross-sectional, questionnaire-based study [19] was conducted among HCPs (doctors, dentists, pharmacists, nurses, midwives, and health officers) at Sabha Medical Center (SMC) and Medical Facilities in Sabha, Libya. Located in Southern Libya, 750 km from Tripoli, SMC is the only teaching hospital in a region with a population of 700,000. The study was conducted from November 1, 2019 to February 29, 2020. The 20-question KAP questionnaire collected demographic information about participating HCPs, their knowledge of and attitudes towards PV, and their practice of reporting ADRs. The self-administered KAP questionnaire was designed based on previous studies [20], [21], [22], [23].

A. Data Collection

Data were collected using a cross-sectional survey from November 2019 to February 2020. In this survey, a total of 200 questionnaires were distributed, and the response rate was 80% (n=160). The participants had one week to read, understand, and respond to the questions.

B. Data Analysis

Both non-parametric statistical tests and the appropriate descriptive statistics for demographic characteristics (mean and standard deviation for age) were performed using SPSS® for Windows, version 16.20. The collected demographic information, which consisted of age, gender, occupation and qualifications, frequencies, and descriptive statistic of each variable, was reported, while the mean and standard deviation were calculated.

C. Ethical Approval

Currently, no ethical committee has overlooked the survey research issues in Libya. As a part of the ethical requirements for this study, the written consent of the participants was obtained before the commencement of the interviews. All participants were assured that their personal information would be kept confidential.

V. Results

The demographic characteristics of respondents are summarized in Table 1 below, which also includes the data regarding the HCPs who voiced their opinions in response to the questions or statements developed for the study. Of the 160 participants, 26.25% were doctors, 17.5% were pharmacists, 13.125% were dentists, 18.75% were laboratory staff, and 24.375% were nurses. Notably, the HCPs consented to participation in this study and responded to the questionnaire.

Table 1.
Baseline characteristics of the study (demographic data)

Characteristics	**Frequency (number) N = 160**
Gender	160
Male	33 (20.625%)
Female	127 (79.375%)
Age-wise distribution (in years)	
20 - 30	82 (51.25%)
30 - 40	45 (28.125%)
40 - 51	28 (17.50%)
≥ 51	5 (3.125%)
Occupation	
Doctors	42 (26.25%)
Pharmacists	28 (17.50%)
Dentists	21(13.125%)
Laboratory Staff	30 (18.75%)
Nurses	39 (24.375%)
Qualification	
Doctorate	10 (6.25%)
Master	11(6.875%)
Bachelor	78 (48.75%)
Higher diploma	34 (21.25%)
Diploma	27 (16.875%)

A. Healthcare Professionals' Knowledge Regarding ADR Reports

Healthcare professionals' knowledge was recorded based on important parameters. As a result, 36.25% of the respondents provided a correct response regarding the definition of PV, while 63.75% provided an incorrect response on this matter. Although 35.625% of the respondents were aware of the importance of PV, it was a different case for 64.375% of the participants. Furthermore, 56.25% of the HCPs possessed knowledge regarding Post Marketing Surveillance (PMS), while 43.75% did not. Moreover, 38.75% of the respondents were aware of the regulatory body responsible for the supervision of ADRs in Libya, but less awareness was observed from 61.25% of the respondents. Although the less known aspects among the HCPs were the existence of the international center for the monitoring of adverse drug reaction, 36.875% and 43.75% of the HCPs were aware that PV included drug-related issues, and blood-related and herbal products. Overall, these results are summarized in Table 2 below.

Table 2.
Knowledge among healthcare professionals regarding ADR report

Knowledge-Related Questions	Correct Response, % N = 160	Incorrect Response, % N = 160
1. Define PV.	58 (36.25%)	102 (63.75%)
2. What is the important purpose of PV?	57 (35.625%)	103 (64.375%)
3. Which of the following methods are commonly employed by the pharmaceutical companies to monitor new drugs' adverse reactions upon their launch in the market?	90 (56.25%)	70 (43.75%)
4. Which regulatory body is responsible for monitoring the ADRs?	62 (38.75%)	98 (61.25%)
5. Where is the location of the international center for adverse drug reaction monitoring?	59 (36.875%)	101 (63.125%)
6. What does pharmacovigilance include?	70 (43.75%)	90 (56.25%)

B. Knowledge among Healthcare Professionals Regarding ADR Reporting

A response rate of 34.375% was recorded regarding banned drugs due to ADR. The awareness of the PV programme in Libya was indicated by 36.25% of the HCPs, leading to constructivism towards PV, as shown in Table 3.

Table 3.
Knowledge among healthcare professionals regarding ADR reporting

Knowledge-Related Questions	Yes N = 160%	No N = 160 %
1. Are you aware of any drug, which has been banned recently due to ADR?	55 (34.375%)	105 (65.625%)
2. Are you aware of the suspected ADRs reporting system in Libya?	58 (36.25%)	102 (63.75%)

C. Healthcare Professionals' Response towards Attitude-Related Questions

A positive attitude towards PV was recorded from the participants, in which 57.50% of the participants perceived that the report of ADR was necessary, while 82.50% opined that a PV centre should be established in every hospital in Libya. Provided that the majority of HCPs (81.875%) suggested that the reporting of ADR was a professional obligation, 82.5% of the participants perceived that ADR reporting should be mandatory. Moreover, 76.25% of the participants believed HCPs should receive adequate exposure to PV. Overall, these results are presented in Table 4 below.

Table 4.
Health care professionals' response towards attitude-related questions

Attitude-Related Questions	Correct Response N = 160%	Incorrect Response N = 160%
1. Who are the HCPs responsible for reporting ADR in a hospital?	92 (57.50%)	68 (42.50%)
2. Is the incorporation of PV in the undergraduate curriculum is important to create awareness among the growing doctors?	132 (82.50%)	28 (17.50%)
3. What is your opinion about the establishment of an ADR monitoring center in every hospital?	131 (81.875%)	29 (18.125%)

4.	Do you think the report of ADR is necessary?	132 (82.50%)	28 (17.50%)
5.	Do you think PV should be taught in detail to healthcare professionals?	122 (76.25%)	38 (23.75%)

D. Factors Deterring ADR Reporting

It can be seen in Table 5 that the factors discouraging HCPs from reporting an ADR included the non-remuneration for reporting (6.5%), lack of time for an ADR report (47.4%), the possible lack of impact from a single unreported case on the ADR database (10.4%), and the challenges in identifying the occurrence of an ADR (35.7 %).

Table 5.
Factors discouraging ADR reporting

Responses				
Which among the following factors discourage you from reporting ADR?	Non-remuneration for reporting	Lack of time for ADR report	The possible absence of impact from a single unreported case on the ADR database	The challenges in identifying the occurrence of ADR
	6.5%	47.4%	10.4%	35.7%

E. Healthcare Professionals' Practice in ADR Reports

As can be seen in Table 6, 5.7% of participants completed an ADR report in their day-to-day clinical practice, while 4.3% had been trained on the methods of reporting ADRs. Although the ADR report was only performed by 8.1% of the participants, 31.2% of the HCPs had observed the form of the ADR report, while 17.3% of the participants stored the records of ADRs. Moreover, 93.4% of the participants expressed their willingness to use the ADR report, indicating signs of logical positivism. Notably, none of the participants ever reported ADRs to the PV center.

Table 6.
Healthcare professionals' responses towards practice-related questions

Practice-Related Questions		**Yes (%)**	**No (%)**
1.	Have you ever seen ADRs among your patients during your professional practices?	7 (4.375%)	153 (95.625%)
2.	Have you ever been trained on the methods of reporting ADR?	9 (5.625%)	151 (94.375%)
3.	Have you ever observed the form of ADR report?	46 (28.75%)	114 (71.25%)
4.	Have you ever reported ADRs to the PV center?	0 (00.00%)	160 (100%)
5.	Do you keep records of ADR?	23 (31.25%)	110 (68.75%)
6.	Are you willing to make ADR reports?	126 (78.75%)	34 (21.25%)

VI. Discussion

Spontaneous reporting is an important method of reporting ADRs in PV programs, in which underreporting is a major challenge [24]. In this reporting method, the KAP of HCPs is assessed, indicating the importance of PV among the HCPs, especially in a regional PV center, as it would represent the level of correct knowledge, attitude, and practice towards ADR reporting.

It was found in a recent study that HCPs exhibit a highly positive attitude towards ADR reporting [24], [25]. However, it was also revealed that all HCPs had poor knowledge regarding various aspects of PV. Notably, these findings were in line with the results of previous studies conducted in several countries, including China, Yemen, Pakistan, India, Nepal, Iran, Nigeria, and Malaysia [26], [27], [28], [29], [30], [31], [32], [33], [34]. According to WHO, these findings can be attributed to the PV programs in the aforementioned countries, as well as in Libya and Palestine, which were in the early stages of implementing and developing PV systems. Although the knowledge among the HCPs in the South-East European countries was adequate, the underreporting of ADR remained a challenge [35].

The current study found that the HCPs exhibit a less positive attitude towards ADR reporting. Although 34.375% of the participants opined that the ADR report was necessary, 36.25% of the participants suggested that it should be made compulsory. This finding indicates the inadequate understanding of the importance of ADR reporting among HCPs. Similar findings were also recorded from the comparison between the results published in different studies [29], [36]. Similarly, the current study showed that 81.875% of the participants emphasized that PV centers should be built in every hospital, while

76.25% of the participants believed that a thorough exposure to PV was important among the HCPs. Overall, this finding was in line with the findings in the studies by Guptaand Udupa [37] and Rajalakshmi et al. [38].

It was recorded in this study that the challenges in identifying the ADRs and inadequate time were the major factors discouraging HCPs from reporting ADRs. This finding was in line with the findings of studies performed in several countries, including India, China, Malaysia, and Nigeria [19], [31], [32], [35], [38]. In contrast, most of the studies performed in European countries, such as England, Ireland, Portugal, and Sweden, and in the United States identified that complacency (the belief that serious ADRs are well documented when a drug is marketed) and fear of litigation were the most notable factors in under-reporting [38], [39], [40], [41]. For example, it is a legal requirement for HCPs in Sweden to report suspected ADRs to authorities. Therefore, the fear of getting involved in a lawsuit was possibly one of the most important factors in under-reporting in this country [42].

The results of this study demonstrate poor practice in the reporting of ADRs. To be specific, 4.37% of participants observed the occurrence of ADR, while only 5.625% were trained in the methods of reporting ADRs. Furthermore, only 28.75% of the participants had observed the form of ADR report forms. Notably, none of the respondents had ever reported ADRs to the PV center. Nevertheless, 31.25% of respondents stored records of ADRs and 78.75% were willing to make ADR reports. Similar results were recorded in various other studies. To be specific, [40] found that similar cases were reported in their study by 20% of participants. Unsatisfactory practices in ADR reporting were also noted in studies by Torwane et al. [34], Gupta et al. [37], Pimpalkhute et al. [43], and Datta et al. [44], 6.1%, 22.8%, 25.0%, and 24.0% of cases, respectively. However, a significant ADR reporting rate of 70% was recorded in England and Sweden, as reporting was crucial in these countries [28].

VII. CONCLUSION

In conclusion, this study showed that most healthcare professionals had poor knowledge and practice in ADR reporting despite the positive attitude towards PV. This lack of knowledge among HCPs was identified as the main challenge to the PV program. Therefore, educational intervention to improve the knowledge and practice of PV and ADR reporting among HCPs is essential. Similarly, the sensitivities of HCPs regarding the importance of PV programs, their responsibilities, and the process of reporting ADRs are crucial. This outcome could be achieved by incorporating topics relating to PV in their undergraduate curriculum. The HCPs also need guidance in how to complete the report forms for ADRs. Moreover, improving the reporting process would also reinforce the practice of PV among HCPs. Spontaneous ADR reporting could be enhanced further by continuous medical education, regular workshops, training, and periodic awareness programs to encourage the reporting of ADRs among HCPs in the future.

REFERENCES

[1] KUMAR, A. (2017) Pharmacovigilance: importance, concepts, and processes. *American Journal of Health System Pharmacy*, 74, pp. 606-612.

[2] INSTITUTE OF MEDICINE (2007) *Preventing medication errors*. Washington, District of Columbia: National Academies Press.

[3] LAZAROU, J., POMERANZ, B.H., and COREY, P.N. (1998) Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. *Journal of the American Medical Association*, 279, pp. 1200-1205.

[4] MOORE, N., LECOINTRE, D., NOBLET, C., and MABILLE, M. (1998) Frequency and cost of serious adverse drug reactions in a department of general medicine. *British Journal of Clinical Pharmacology*, 45, pp. 301-308.

[5] KONGKAEW, C., NOYCE, P.R., and ASHCROFT, D.M. (2008) Hospital admissions associated with adverse drug reactions: A systematic review of prospective observational studies. *Annals of Pharmacotherapy*, 42 (7), pp. 1017-1025.

[6] BEIJER, H.J.M. and DE BLAEY, C.J. (2002) Hospitalisations caused by adverse drug reactions (ADR): a meta-analysis of observational studies. *Pharmacy World and Science*, 24, pp. 46-54.

[7] ALSHAMMARI, T.M. (2016) Drug safety: The concept, inception and its importance in patients' health. *Saudi Pharmaceutical Journal*, 24 (4), pp. 405-412.

[8] KHAN, T.M. (2013) Community pharmacists' knowledge and perceptions about adverse drug reactions and barriers towards their reporting in Eastern region, Alahsa, Saudi Arabia. *Therapeutic Advances in Drug Safety*, 4 (2), pp. 45-51.

[9] GIDEY, K., SEIFU, M., and HAILU, B.Y. (2019) Healthcare professionals knowledge, attitude and practice of adverse drug reactions reporting in Ethiopia: a cross-sectional study. *BMJ Open*, 10, e034553.

[10] COLEMAN, J.J. and PONTEFRACT, S.K. (2016) Adverse drug reactions. *Clinical Medicine Journal*, 16 (5), pp. 481-485.

[11] GIARDINA, C., CUTRONEO, P.M., and MOCCIARO, E. (2018) Adverse Drug Reactions in Hospitalized Patients: Results of the FORWARD (Facilitation of Reporting in Hospital Ward) Study. *Frontiers in Pharmacology*, 29, 350.

[12] KONGKAEW, C., NOYCE, P.R., and ASHCROFT, D.M. (2008) Hospital admissions associated with adverse drug reactions: a systematic review of prospective observational studies. *Annals of Pharmacotherapy*, 42 (7), pp. 1017-1025.

[13] AL HAMID, A., GHALEB, M., ALJADHEY, H., and ASLANPOUR, Z. (2014) A systematic review of hospitalization resulting from medicine-related problems in adult patients. *British Journal of Clinical Pharmacology*, 78, pp. 202-217.

[14] BOUVY, J., BRUIN, M., and KOOPMANSCHAP, M. (2015) Epidemiology of Adverse Drug Reactions in Europe: A Review of Recent Observational Studies. *Drug Safety*, 38, pp. 437-453.

[15] PEREZ-RICART, A., GEA-RODRIGUEZ, E., ROCA-MONTANANA, A., GIL-MANEZ, E., and PEREZ-FELIU, A. (2019) Integrating pharmacovigilance into the routine of pharmacy department: experience of nine years. *Farm Hospital*, 43 (4), pp. 128-133.

[16] KAEDING, M., SCHMÄLTER.J., and KLIKA, C. (2017) *Pharmacovigilance in the European Union: practical implementation across member states*. Cham: Springer.

[17] LAZAROU, J., POMERANZ, B.H., a nd COREY, P.N. (1998) Incidence of adverse drug reactions in hospitalized patients—a meta-analysis of prospective studies. *Journal of the American Medical Association*, 279, pp. 1200-1205.

[18] TANGIISURAN, B., GOZZOLI, M.P., DAVIES, J., and RAJKUMAR, C. (2010) Adverse drug reactions in older people. *Reviews in Clinical Gerontology*, 20, pp. 246-259.

[19] GUPTA, S.K., NAYAK, R.P., SHIVARANJANI, R., and VIDYARTHI, S.K. (2015) A questionnaire study on the knowledge, attitude and the practice of pharmacovigilance among the healthcare professionals in a teaching hospital in South India. *Perspectives in Clinical Research*, 6, pp. 45-52.

[20] HAZELL, L. and SHAKIR, S.A. (2006) Under-reporting of adverse drug reactions. *Drug Safety*, 29 (5), pp. 385-396.

[21] DESAI, C.K., IYER, G., PANCHAL, J., SHAH, S., and DIKSHIT, R.K. (2011) An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. *Perspectives in Clinical Research*, 2 (4), pp. 129-136.

[22] ALSHAMMARI, T.M., ALAMRI, K.K., GHAWA, Y.A., ALOHALI, N.F., ABUALKOL, S.A., and ALJADHEY, H.S. (2015) Knowledge and attitude of healthcare professionals in hospitals towards pharmacovigilance in Saudi Arabia. *International Journal of Clinical Pharmacy*, 37, pp. 1104-1110.

[23] GANESAN, S., SANDHIYA, S., REDDY, K.C., SUBRAHMANYAM, D.K., and ADITHAN, C. (2017) The Impact of the Educational Intervention on Knowledge, Attitude, and Practice of Pharmacovigilance toward Adverse Drug Reactions Reporting among Healthcare Professionals in a Tertiary Care Hospital in South India. *Journal of Natural Science, Biology and Medicine*, 8 (2), pp. 203-209.

[24] SANTOSH, K.C., TRAGULPIANKIT, P., EDWARDS, I., and GORSANAN, S. (2013) Knowledge about adverse drug reactions reporting among healthcare professionals in Nepal.

International Journal of Risk & Safety in Medicine, 25, pp. 1-16.
[25] SRINIVASAN, V., SHEELA, D., and MRIDULA, D. (2017) Knowledge, attitude and practice of pharmacovigilance among the healthcare professionals in a tertiary care hospital. *Biomedical and Pharmacology Journal*, 10, pp. 1441-1447.
[26] ALSHAKKA, M., BASSALIM, H., and ALSAKKAF, K. (2016) Knowledge and Perception towards Pharmacovigilance among Healthcare Professionals in Tertiary Care Teaching Hospital in Aden, Yemen. *Journal of Pharmacy Practice and Community Medicine*, 2, pp. 21-28.
[27] AZIZ, Z., SIANG, T.C., and BADARUDIN, N.S. (2007) Reporting of adverse drug reactions: Predictors of under-reporting in Malaysia. *Pharmacoepidemiology and Drug Safety*, 16, pp. 223-228.
[28] HANAFI, S., TORKAMANDI, H., HAYATSHAHI, A., GHOLAMI, K., and JAVADI, M. (2012) Knowledge, attitudes and practice of nurse regarding adverse drug reaction reporting. *Iranian Journal of Nursing and Midwifery Research*, 17, pp. 21-25.
[29] KHAN, S.A., GOYAL, C., CHANDEL, N., and RAFI, M. (2013) Knowledge, attitudes and practice of doctors to adverse drug reaction reporting in a teaching hospital in India: an observational study. *Journal of Natural Science, Biology and Medicine*, 4, pp. 191-196.
[30] LI, Q., ZHANG, S.M., and CHEN, H.T. (2004) Awareness and attitudes of healthcare professionals in Wuhan, China to the reporting of adverse drug reactions. *Chinese Medical Journal*, 117, pp. 856-861.
[31] NISA, Z.U., ZAFAR, A., and SHER, F. (2018) Assessment of knowledge, attitude and practice of adverse drug reaction reporting among healthcare professionals in secondary and tertiary hospitals in the capital of Pakistan. *Saudi Pharmaceutical Journal*, 26, pp. 453-461.
[32] OSHIKOYA, K.A. and AWOBUSUYI, J.O. (2009) Perceptions of doctors to adverse drug reaction reporting in a teaching hospital in Lagos, Nigeria. *BMC Clinical Pharmacology*, 9, pp. 14-22.
[33] PALAIAN, S., IBRAHIM, M.I., and MISHRA, P. (2011) Health professionals knowledge, attitude and practices towards pharmacovigilance in Nepal. *Pharmacy Practice*, 9, pp. 228-235.
[34] TORWANE, A.N., SUDHIR, H., GOURAHA, A., JAIN, S., CHAVAN, K., and DAYMA, A. (2015) Assessment of knowledge, attitude and practice related to pharmacovigilance among the healthcare professionals in a teaching hospital in central India: an questionnaire study. *Pharmaceutical Sciences World*, 4, pp. 785-799.
[35] KOZAMERNIK, B. (2010) Spontaneous adverse drug reaction reporting: attitudes and practice of healthcare professionals and distributors in South East European region. *Farmacevtski Vestnik*, 61, pp. 271-281.
[36] SRINIVASAN, V., SHEELA, D., and MRIDULA, D. (2017) Knowledge, Attitude and Practice of Pharmacovigilance among the Healthcare Professionals in a Tertiary Care Hospital – A Questionnaire Study. *Biomedical & Pharmacology Journal*, 10 (3), pp. 1441-1447.
[37] GUPTA, P. and UDUPA, A. (2011) Adverse drug reaction reporting and pharmacovigilance: knowledge, attitudes and perceptions amongst resident doctors. *Journal of Pharmaceutical Sciences*, 3, pp. 1064-1069.
[38] RAJALAKSHMI, R., VASUDHARADEVI, B., PRASAD, T.S.D., SWETHA, S., and DHARINI, B. (2017) Knowledge, attitude and practice towards pharmacovigilance and adverse drug reaction reporting among nurses in a tertiary care hospital, tirupati. *International Journal of Pharmaceutical and Clinical Research*, 9, pp. 683-689.
[39] BELTON, K.J. (1997) European Pharmacovigilance Research group: Attitude survey of adverse drug-reaction reporting by healthcare professionals across the European union. *European Journal of Clinical Pharmacology*, 52, pp. 423- 427.
[40] BACKSTROM, M., EKMAN, E., and MJORNDAL, T. (2007) Adverse drug reaction reporting by nurses in Sweden.

European Journal of Clinical Pharmacology, 63, pp. 613-618.
[41] VALLANO, A., CEREZA, G., PEDROS, C., AGUSTI, A., DANES, I., and AGUILERA, C. (2005) Obstacles and solutions for spontaneous reporting of adverse drug reactions in the hospital. *British Journal of Clinical Pharmacology*, 60, pp. 653-658.
[42] GAVAZA, P., BROWN, C.M., and KHOZA, S. (2010) Texas pharmacists' opinions on reporting serious adverse drug events to the Food and Drug Administration: a qualitative study. *Pharmaceutical Sciences World*, 3, pp. 651-657.
[43] PIMPALKHUTE, S.A., JAISWAL, K.M., SONTAKKE, S.D., BAJAIT, C.S., and GAIKWAD, A. (2012) Evaluation of awareness about pharmacovigilance and adverse drug reaction monitoring in resident doctors of a tertiary care teaching hospital. *Indian Journal of Medical Sciences*, 66, pp. 55-61.
[44] DATTA, S. and SENGUPTA, S. (2016) An evaluation of knowledge, attitude and practice of adverse drug reaction reporting in a tertiary care teaching hospital of Sikkim. *Perspectives in Clinical Research*, 6, pp. 200-206.

参考文:

[1] KUMAR，A.（2017）药物警戒：重要性，概念和过程。美国卫生系统药学杂志，74，第 606-612 页。
[2] 医学研究院（2007）预防用药错误。华盛顿哥伦比亚特区：国家科学院出版社。
[3] J. LAZAROU，B.H。POMERANZ 和 P.N. COREY。（1998）住院患者中药物不良反应的发生率：前瞻性研究的荟萃分析。美国医学会杂志，279，第 1200-1205 页。
[4] MOORE，N.，LECOINTRE，D.，NOBLET，C. 和 MABILLE，M.（1998）普通医学系严重药物不良反应的发生频率和费用。英国临床药理学杂志，45，第 301-308 页。
[5] C. KONGKAEW，P.R。NOYCE 和 D.M. ASHCROFT。（2008）与药物不良反应相关的住院：前瞻性观察研究的系统综述。药物治疗学年鉴，42（7），第 1017-1025 页。
[6] BEIJER，H.J.M. 和 DE BLAEY，C.J.（2002）药物不良反应（ADR）引起的住院：观察性研究的荟萃分析。药学世界与科学，24，第 46-54 页。
[7] ALSHAMMARI，T.M.（2016）药物安全性：概念，开始及其对患者健康的重要性。沙特药物杂志，24（4），第 405-412 页。
[8] KHAN，T.M。（2013）在东部地区，沙特阿拉伯的阿拉萨，社区药剂师对药物不良反应的认识和看法以及对其报告的障碍。药物安全性的治疗进展，4 (2)，第 45-51 页。
[9] KIDE，GIDEY，M。SEIFU 和 B.Y. HAILU。（2019）埃塞俄比亚医疗保健专业人员的不良药物反应报告的知识，态度和做法：一项横断面研究。英国医学杂志公开赛，10，e034553。
[10] 科尔曼，J.J。和 PONTEFRACT，S.K.（2016）药物不良反应。临床医学杂志，16（5），第 481-485 页。
[11] GIARDINA，C.，CUTRONEO，P.M. 和 MOCCIARO，E.（2018）住院患者的药物不良反应：向前（在医院病房中进行报告的便利）研究的结果。药理学前沿，29，350。
[12] C. KONGKAEW，P.R。NOYCE 和 D.M. ASHCROFT。（2008）与药物不良反应相关的住院：对前瞻性观察研究的系统评价。药物治疗学年鉴，42（7），第 1017-1025 页。
[13] AL HAMID，A.，GHALEB，M.，ALJADHEY，H. 和 ASLANPOUR，Z.（2014）对成年患者因药物相关问题而住院的系统评价。英国临床药理学杂志，78，第 202-217 页。
[14] BOUVY，J.，BRUIN，M. 和 KOOPMANSCHAP，M.（2015）欧洲不良药物反应的流行病学：最近的观察性研究综述。药物安全，38，第 437-453 页。
[15] A. PEREZ-RICART，E。GEA-RODRIGUEZ，A。ROCA-MONTANANA，

E。GIL-MANEZ 和 A. PEREZ-FELIU。（2019）将药物警戒性纳入药房常规：九年的经验。农场医院，43（4），第 128-133 页。
[16] M. KAEDING，J。SCHMÄLTER. J。和 KLIKA，C。（2017）欧盟的药物警戒：跨成员国的实际实施。湛：施普林格。
[17] J. LAZAROU，B.H.的 POMERANZ 和 P.N.的 COREY。（1998）住院患者中药物不良反应的发生率—前瞻性研究的荟萃分析。美国医学会杂志，279，第 1200-1205 页。
[18] TANGIISURAN，B.，GOZZOLI，MP。，DAVIES，J。和 RAJKUMAR，C。（2010）老年人的药物不良反应。临床老年医学评论，20，第 246-259 页。
[19] S.K. GUPTA，R.P。NAYAK，R。SHIVARANJANI 和 S.K. VIDYARTHI。（2015）对印度南部一家教学医院的医疗保健专业人员进行药物警戒的知识，态度和实践的问卷调查。临床研究展望，6，第 45-52 页。
[20] HAZELL，L. 和 SHAKIR，S.A.（2006）药物不良反应报告不足。药物安全，29（5），第 385-396 页。
[21] DESAI，C.K.，IYER，G.，PANCHAL，J.，SHAH，S. 和 DIKSHIT，R.K.（2011）对三级医院处方药中不良药物反应报告的知识，态度和实践进行评估。临床研究展望，2 (4)，第 129-136 页。
[22] T.M. ALSHAMMARI，K.K 。ALAMRI，Y.A。N.F. ALOHALI，S.A。ABUALKOL 和 H.S. ALJADHEY 的 YAL。（2015）沙特阿拉伯医院中医护人员对药物警戒的知识和态度。国际临床药学杂志，37，第 1104-1110 页。
[23] GANESAN，S.，SANDHIYA，S.，REDDY，K.C.，SUBRAHMANYAM，D.K.，和 ADITHAN，C.（2017）教育干预对药物警戒对药物不良反应报告的知识，态度和实践的影响印度南部三级医院的医护人员。自然科学，生物学和医学杂志，8（2），第 203-209 页。
[24] K.C. SANTOSH，P. TRAGULPIANKIT，爱德华兹和 S. GORSANAN（2013）有关尼泊尔医疗保健专业人员中药物不良反应报告的知识。国际医学风险与安全杂志，25，第 1-16 页。
[25] SRINIVASAN，V.，SHEELA，D. 和 MRIDULA，D.（2017）三级医院的医疗保健专业人员中的药物警戒知识，态度和实践。生物医学和药理学杂志，10，第 1441-1447 页。
[26] ALSHAKKA，M.，BASSALIM，H. 和 ALSAKKAF，K.（2016）也门亚丁第三级教学医院的医疗保健专业人员对药物警戒的认识和认识。药学实践与社区医学杂志，2，第 21-28 页。
[27] Z. AZIZ，T.C. SIANG 和 N.S. BADARUDIN（2007）药品不良反应的报告：马来西亚漏报的预测因素。药物流行病学和药物安全，16，第 223-228 页。
[28] HANAFI，S.，TORKAMANDI，H.，HAYATSHAHI，A.，GHOLAMI，K. 和 JAVADI，M.（2012）护士关于不良药物反应报告的知识，态度和实践。伊朗护理和助产学杂志，17，第 21-25 页。
[29] KHAN，S.A.，GOYAL，C.，和 CHANDEL, N.（2013）印度教学医院医生对药物不良反应报告的知识，态度和实践：一项观察性研究。自然科学，生物学和医学杂志，4，第 191-196 页。
[30] 李强，张超和陈海涛。（2004）中国武汉医护人员对不良药物反应报告的认识和态度。中华医学杂志，117，第 856-861 页。
[31] NISA，Z.U.，ZAFAR，A. 和 SHER，F.（2018）在巴基斯坦首都二线和三级医院的医疗保健专业人员中评估药物不良反应报告的知识，态度和做法。沙特制药杂志，26，第 453-461 页。
[32] OSHIKOYA，K.A。和 AWOBUSUYI，J.O。（2009）在尼日利亚拉各斯的一家教学医院中医生对药物不良反应报告的看法。BMC 临床药理学，9，第 14-22 页。
[33] PALAIAN，S.，IBRAHIM，M.I.，和 MISHRA，P.（2011）尼泊尔卫生专业人员对药物警戒的知识，态度和做法。药学实践，9，第 228-235 页。

[34] TORWANE，A.N.，SUDHIR，H.，GOURAHA，A.，JAIN，S.，CHAVAN，K。和 DAYMA，A。（2015）对以下地区的医护人员进行有关药物警戒的知识，态度和实践的评估印度中部的一家教学医院：问卷调查。药学世界，4，第 785-799 页。

[35] KOZAMERNIK，B.（2010）自发性药物不良反应报告：东南欧地区医务人员和分销商的态度和做法。法玛切夫斯基·维斯尼克，61，第 271-281 页。

[36] SRINIVASAN，V.，SHEELA，D.,和 MRIDULA，D.（2017）三级护理医院医疗保健专业人员中药物警戒的知识，态度和实践–问卷调查。生物医学与药理学杂志，10（3），第 1441-1447 页。

[37] GUPTA，P. 和 UDUPA，A.（2011）药物不良反应报告和药物警戒：常驻医生中的知识，态度和看法。药物科学杂志，3，第 1064-1069 页。

[38] RAJALAKSHMI，R.，VASUDHARADEVI，B.，PRASAD，TSD，SWETHA，S。，和 DHARINI，B。（2017）三级医院护士对药物警戒和药物不良反应报告的知识，态度和做法，蒂鲁伯蒂。国际药物和临床研究杂志，9，第 683-689 页。

[39] BELTON，K.J。（1997）欧洲药物警戒研究小组：整个欧盟的医疗保健专业人员对不良药物反应报告的态度调查。欧洲临床药理学杂志，52，第 423-427 页。

[40] M. BACKSTROM，E. EMAN 和 T. MJORNDAL（2007）瑞典护士的不良药物反应报告。欧洲临床药理学杂志，63，第 613-618 页。

[41] VALLANO，A.，CEREZA，G.，PEDROS，C.，AGUSTI，A.，DANES，I.和 AGUILERA，C.（2005）在医院自发报告药物不良反应的障碍和解决方案。英国临床药理学杂志，60，第 653-658 页。

[42] GAVAZA，P.，BROWN，C.M. 和 KHOZA，S.（2010）德州药剂师关于向食品和药物管理局报告严重药物不良事件的观点：一项定性研究。药学世界，3，第 651-657 页。

[43] PIMPALKHUTE，S.A.，JAISWAL，K.M.，SONTAKKE，S.D.，BAJAIT，C.S.和 GAIKWAD，A.（2012）对三级教学医院住院医生对药物警戒和药物不良反应监测的认识评估。印度医学杂志，66，第 55-61 页。

[44] DATTA，S. 和 SENGUPTA，S.（2016）在锡金三级教学医院对药物不良反应报告的知识，态度和实践进行评估。临床研究的观点，6，第 200-206 页。