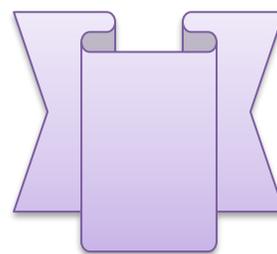
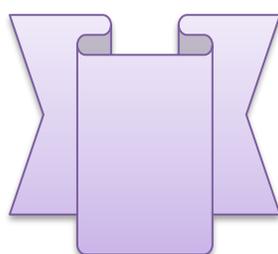
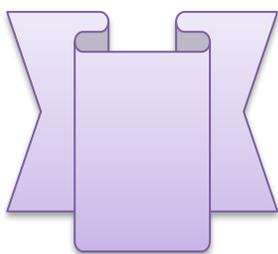
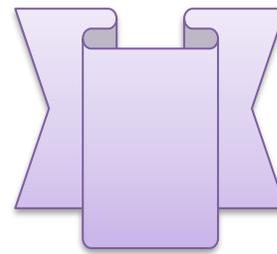
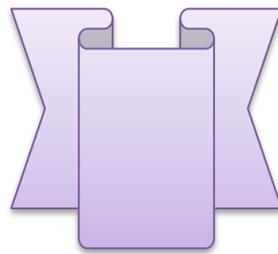
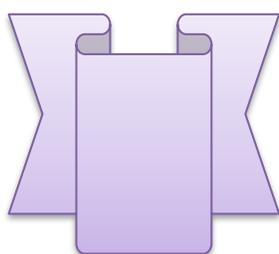
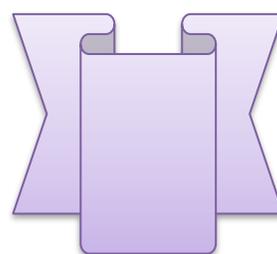
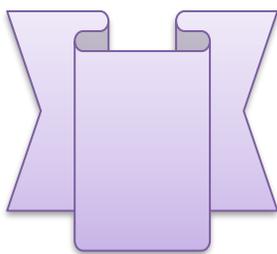
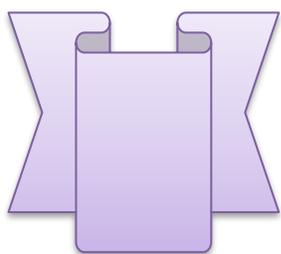


INTERNATIONAL JOURNAL OF MEDICAL ARTS



Volume 5, Issue 9, September 2023

<https://ijma.journals.ekb.eg/>



Print ISSN: 2636-4174

Online ISSN: 2682-3780



Available online at Journal Website
<https://ijma.journals.ekb.eg/>
 Main Subject [Pharmacology]



Original Article

Awareness of Digital Reporting of Adverse Drug Events among Health Care Professionals

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ABSTRACT

Article information

Received: 04-09-2023

Accepted: 18-10-2023

DOI:
10.21608/IJMA.2023.234030.1801.

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Citation: Sharma S, Yadav DK, Singh AK, Pandey M, Singh KK. Awareness of Digital Reporting of Adverse Drug Events among Health Care Professionals. IJMA 2023 September; 5 [9]: 3676-3681. doi: 10.21608/IJMA.2023.234030.1801.

Background: Digital reporting of adverse events remains the most important tool to improve pharmacovigilance information related to drugs introduced in the market with good efficacy and limited safety knowledge perceived from clinical trials.

Aim of the Study: The study aimed to identify the knowledge and awareness of digital reporting of adverse drug events among healthcare professionals working at a tertiary care hospital in India.

Materials and Methods: A cross-sectional descriptive questionnaire-based study was conducted with Physicians, Pharmacists, Technicians and Nurses. The questionnaire comprised items regarding awareness of pharmacovigilance and digital reporting of ADRs and perception and attitudes of healthcare professionals in digital reporting of adverse drug events. Descriptive statistics were used to analyse the data.

Results: Healthcare professionals received 200 questionnaires in total, and 200 participants responded, yielding a 100% response rate among which 108 were male and 92 were female. 98 doctors, 32 pharmacists, 11 technicians, and 59 nurses comprised the group of healthcare professionals. 72% of healthcare professionals were familiar with the phrase "pharmacovigilance." Nearly 73% of healthcare professionals did not know the method of digital reporting of ADR and their nearby pharmacovigilance centers. In addition, 88% agreed that ADRs need to be reported digitally because it is easy and convenient and 92% agreed that it is their professional responsibility.

Conclusion: Our study shows that awareness of pharmaco-vigilance and digital ADR reporting among healthcare professionals is relatively low.

Keywords: Pharmacovigilance; Adverse drug events; Questionnaire; Physicians; Pharmacists.



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INTRODUCTION

Spontaneous reporting is the most popular reporting procedure for pharmacovigilance. The main objective of systems for reporting spontaneously emerging adverse drug reactions [ADRs] is to detect early warning signs of uncommon, novel, and severe adverse drug reactions [1]. The World Health Organization [WHO] defines pharmacovigilance [PV] as “the science and activities related to the detection, assessment, understanding and prevention of adverse effects of medications” [2]. Several dangerous adverse drug reactions [ADRs] associated with medicine use are unreported or not noticed by regulatory authorities [3]. Patient safety is seriously compromised by the underreporting of ADRs, which places a heavy burden on healthcare systems [3, 4]. The majority of the Pharmacovigilance reporting methods are digital which are spontaneous and voluntary [5].

Following the thalidomide tragedy, the safety of pharmaceutical products was closely scrutinized based on their effectiveness. In 1968, the World Health Organization [WHO] launched the WHO Program for International Drug Monitoring, which served as a catalyst for the globalization of pharmacovigilance studies. This initiative facilitates in the analysis of information obtained from individual reports and offers a forum for WHO members to work collectively on monitoring the safety of pharmaceutical goods. Individual case safety reports [ICSR] sent by health care professionals [HCPs] to the central WHO global database, VigiBase, which is maintained and managed by the Uppsala Monitoring Center, Sweden, are collected by the national pharmacovigilance centers developed by the countries and approved by the WHO. The most crucial method for enhancing pharmacovigilance data on medications with promising efficacy but scant information on their potential side effects from clinical trials is digital reporting of adverse events. Although regulatory agencies in several countries have created procedures for spontaneous reporting to encourage and promote reporting by HCPs, the percentage of adverse event reporting remains low [6-9].

To avoid adverse reactions caused by drugs, ADR underreporting must be improved. This remains not only a person's health-related burden, also results in an increased economic burden on the limited available healthcare resources [10]. In addition, this is also unethical for not informing

or reporting the hazardous effects of a drug after prescription. This may have caused a same ADR in another individual [11]. Declaring a possible ADR is an ethical responsibility for every healthcare professional that arises based on the idea of doing no harm to the patient. Hence utmost importance must be given by the HCPs in their daily practice.

Considering the rising trend of under-reporting, Drug Controller of India [DCGI] while being supervised by Indian Pharmacopoeia Commission [IPC], introduced a National Programme on Adverse Drug Reactions [ADR] reporting named as Pharmacovigilance Program of India [PvPI] in the year 2014 [12, 13]. Although numerous adverse drug reaction reporting centers have been established across the nation in Zonal, Divisional, and Peripheral locations under the strict oversight of the DCGI, adverse drug events are still under-reported [14]. This is mainly due a lack in understanding towards ADRs and reporting of ADR among HCPs, which has also been reported from many other studies done across the world [15].

The aim of the study is to identify the knowledge and awareness of digital reporting of adverse drug events among healthcare professionals working at a tertiary care hospital in India.

PATIENTS AND METHODS

A cross-sectional descriptive questionnaire-based study was conducted after getting approval from the Institutional Ethics Committee. A Self-developed, pre-validated questionnaire consisting of both open-ended and close-ended items was given to a total of 200 healthcare professionals from different specialties of a Tertiary Care Teaching Medical College Hospital and fill up after explaining the nature and purpose of the study. Written informed consent was obtained from each participant. Healthcare professionals refused to give written consent were excluded from the study.

The HCP groups were Physicians, Pharmacists, Technicians and Nurses. A total of 26 questions consisting of multiple-choice statements was given. Two sets of closed questions were used to measure knowledge. Each set of closed questions contained eight statements and respondents were asked to respond ‘yes’, ‘no’ or ‘don’t know’ to each statement. The first set related to ADR reporting. At the end of the

study, all the data were pooled and expressed as counts and percentages. Univariate analysis, which explores each variable in a data set separately, was carried out using the fisher's exact test. A probability value of <0.05 was considered significant.

RESULTS

The distribution of 200 questionnaires to healthcare professionals resulted in a response rate of 100%, with 108 males and 92 females among those who completed the questionnaires [figure 1]. The healthcare professionals included 98 physicians, 59 nurses, 32 pharmacists, and 11 technicians [figure 2]. The questionnaires were gathered, online and on-site at the hospital.

Awareness of Pharmacovigilance and Digital Reporting of Adverse Drug Reactions [ADR]: Healthcare professionals were questioned about their knowledge of the terms "pharmacovigilance," "ADRs," and the types of ADRs that need to be reported. The term "pharmacovigilance" was known to the majority of healthcare professionals [72%] in this study. The greatest percentage of pharmacovigilance awareness was found among Physicians [80.5%], followed by Nurses [9.5%], Pharmacists [8%] and Technicians [2%]. The majority of participants [70.5%] properly responded to the question on the definition of pharmacovigilance. ADRs definition was correctly answered by around 56% of study participants, and 46% were aware of types of ADRs that is to be reported. The questionnaire also included whether they were aware of the digital ADR reporting mechanism, as well as their nearby ADR reporting centers. A question also included whether they have attended any CMEs and workshops in pharmacovigilance. Most of the healthcare

professionals [73%] does not know the method of digital reporting of ADR and their nearby pharmacovigilance center and almost 88% have not attended any CMEs or workshops [figure 3].

Perception and Attitude Toward Healthcare Professionals in Digital Reporting of Adverse Drug Reactions: When asked whether it is their professional responsibility to report ADRs online, 88% of healthcare professionals responded positively since it is easy and convenient and 92% agreed that it is their professional responsibility. Additionally, pharmacovigilance's inclusion in the undergraduate curriculum was a question that received a 75% "yes" response [figure 4].

Practices of Digital ADR Reporting: The healthcare professionals were questioned about various monitoring systems, reporting forms, whether or not they had digitally reported ADRs, where to get the forms, whom to report the ADRs to, and what other things could deter them from reporting ADRs. Concerning monitoring methods, 42% of research participants were not familiar with the hospital's ADR reporting system. Further 86% has never reported or submitted any ADR, and 72% were unable to locate the form collection location. Regarding the query of to whom the ADR should be reported, 47% answered as Pharmacology department, 32% answered as Hospital super-intendent, 15% answered as Drug Company, 6% answered as prescriber. Finally, the reasons that deter study participants from reporting ADRs were questioned and 65% did not know how to digitally report an ADR, 15% did not accept that it is important to report ADR, 12% answered that managing patients is more important and 8% said that patient may have confidentiality issues.

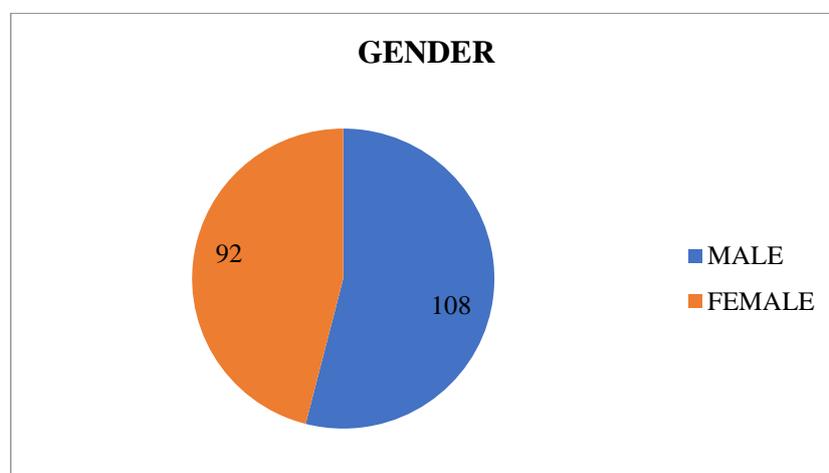


Figure [1]: Gender characteristics of respondents

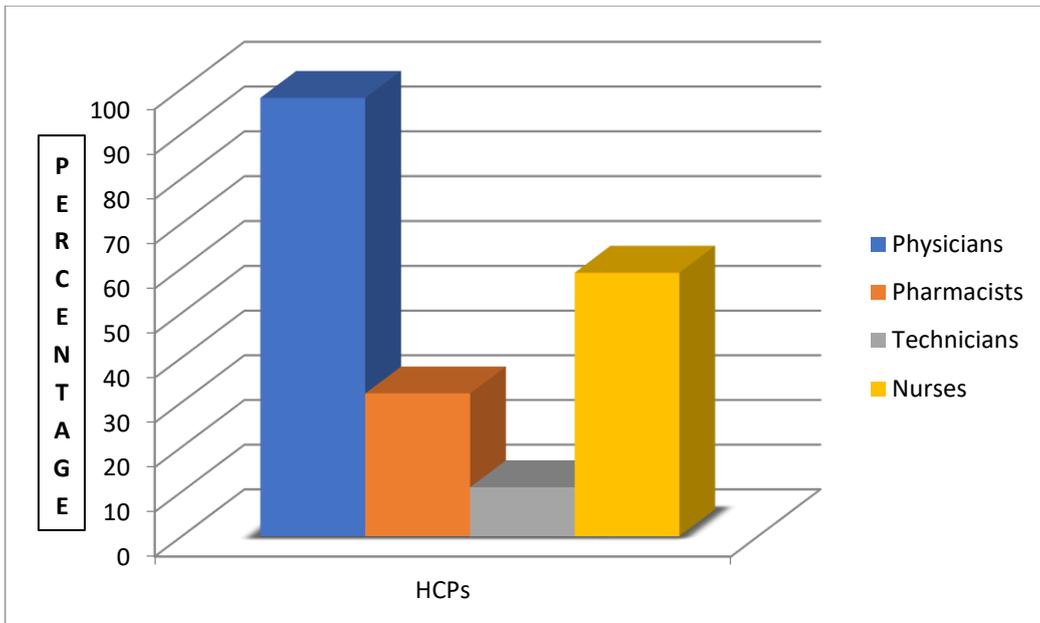


Figure [2]: Percentage of respondents among the study population

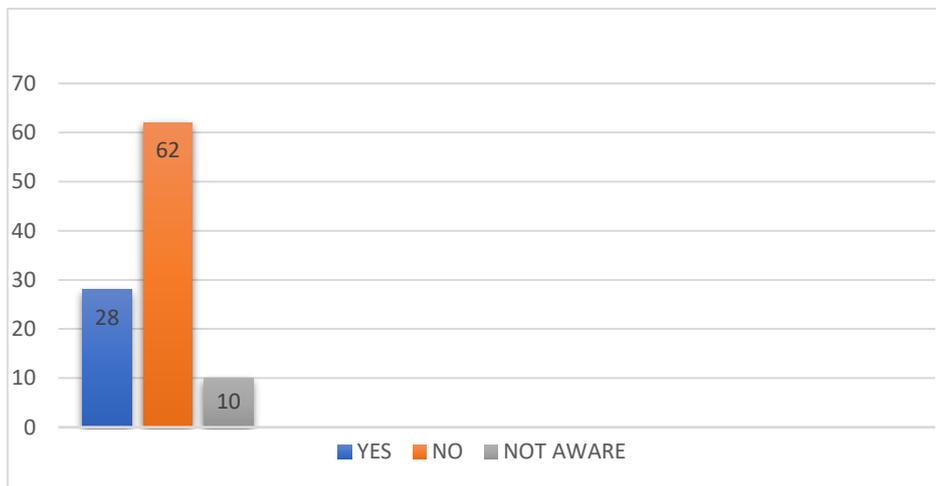


Figure [3]: Percentage of awareness of the healthcare professionals in pharmacovigilance and digital reporting of Adverse Drug Reactions

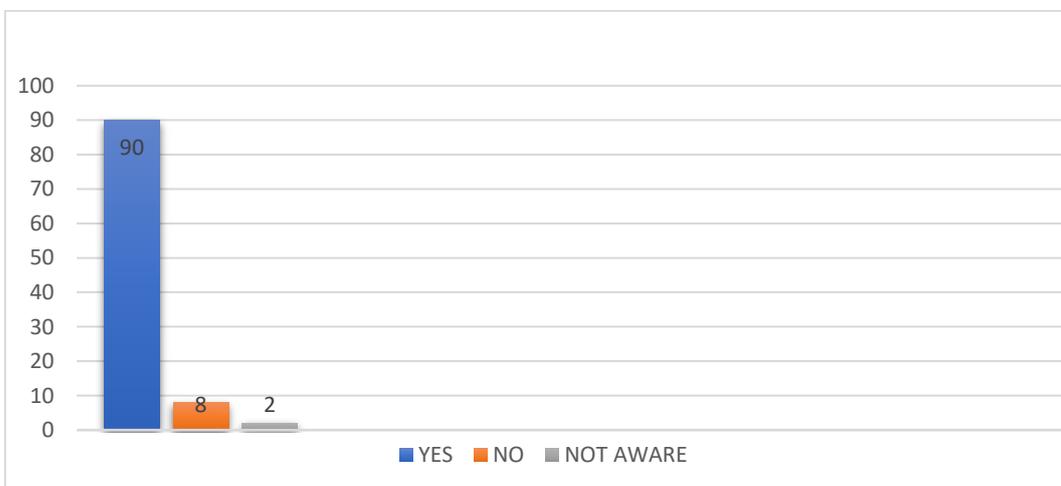


Figure [4]: Percentage of perception and attitude of the healthcare professionals in digital reporting of adverse drug events

DISCUSSION

Adverse medication responses are the leading reason for patient harm in the healthcare system. Most of the ADRs are preventable but might have a probability of occurring again. ADRs are still among the top 10 cause of fatality in numerous countries [16]. To avoid or reduce patient harm, advances in public health and the availability of methods for assessing and tracking the safety of pharmaceuticals in clinical settings are essential. Establishing an effective ADR reporting system is necessary to make this better. We performed a questionnaire survey at our hospital to determine healthcare personnel' knowledge and understanding of the digital reporting of adverse medication occurrences. In contrast to other studies that have been reported, our study's response rate was 100%, which is high [17, 18]. Our findings also indicated that healthcare workers lacked awareness and information. Additionally, this outcome is consistent with research from other nations' studies indicating the need for Pharmacovigilance workshops among healthcare professionals, especially to enhance drug safety among general population [19]. A pilot survey was performed among private doctors in India of which 600 questionnaires were given and 332 medical professionals replied to the survey.

This study highlighted the requirement and necessity to improve ADR reporting for awareness among doctors and highlighted their lack of understanding of pharmacovigilance as well as the attitudes that lead to significant underreporting among them [18]. A cross-sectional survey was performed by another study to assess their awareness and expertise about healthcare professionals regarding pharmacovigilance in government and private hospitals. The results of this investigation revealed a lack of pharmacovigilance knowledge and the need for a pharmacovigilance training program. ADR underreporting is a global issue, according to numerous previous researches, including in nations like the United Kingdom where pharmacovigilance monitoring systems are well-established [20, 21]. Despite the fact that the majority of healthcare workers are prepared to report ADRs on time by understanding the necessity of reporting them, a few causes of underreporting include ignorance of reporting procedures. They feel reporting an ADR is not required of them, hence their hospital must have ADR forms available [17]. The inclusion of a pharmacovigilance training program in undergraduate

curricula by HCPs should also be mandated as doing so will improve the understanding and awareness of the next generation of healthcare professionals and result in better patient care. Additionally, accurate pharmacovigilance and computerized ADR reporting systems in clinical practice will result in the use of medicines that is supported by evidence and as a result, there is a greater chance of eliminating many ADRs. HCPs are vital for the success of pharmacovigilance programs. HCPs need to receive training on the stages involved in digital ADR reporting in order to further improve the process.

Additionally, advancements in digital ADR reporting will eventually lessen the burden of health care. All HCPs should be encouraged to submit ADR reports electronically utilizing PvPI forms or by notifying the Clinical Pharmacology department. Since the sample size was so small, we employed and the fact that our hospital was the only study site, our study has multiple limitations.

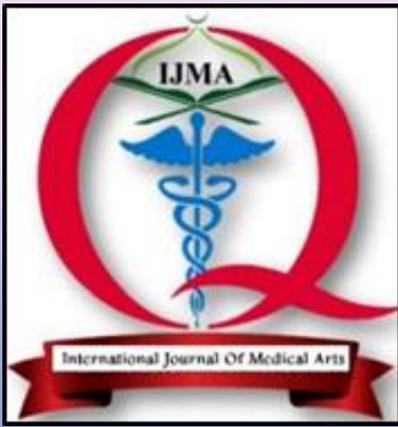
Conclusions: The findings of our current study indicate that healthcare professionals know relatively little about pharmacovigilance and digital reporting of ADRs. This reflects the necessity to improve the knowledge and awareness of pharmacovigilance. This can be accomplished by giving healthcare professionals elective training courses, CMEs, and seminars. Additionally, patient participation is required to enhance knowledge, attitudes, and perceptions about adverse drug events which will further increase the number of ADR reports leading to a positive impact on overall patient care.

Financial and non-financial relations and activities of interest: None

REFERENCES

1. World Health Organization. Safety Monitoring of Medicinal Products: Reporting System for the General Public. [2012].
2. Lardon J, Abdellaoui R, Bellet F, Asfari H, Souvignet J, Texier N, *et al.* Adverse Drug Reaction Identification and Extraction in Social Media: A Scoping Review. *J Med Internet Res.* 2015 Jul 10;17[7]:e171. doi: 10.2196/jmir.4304.
3. Ribeiro-Vaz I, Silva AM, Costa Santos C, Cruz-Correia R. How to promote adverse drug reaction reports using information systems - a systematic review and meta-analysis. *BMC Med Inform Decis*

- Mak. 2016 Mar 1;16:27. doi: 10.1186/s12911-016-0265-8.
4. Phillips AL, Nigro O, Macolino KA, Scarborough KC, Doecke CJ, Angley MT, Shakib S. Hospital admissions caused by adverse drug events: an Australian prospective study. *Aust Health Rev.* 2014 Feb;38[1]:51-7. doi: 10.1071/AH12027.
 5. Fossouo J, McDonald R, Wickramasinghe N. Leveraging information technology in pharmacovigilance: benefits for pharmacists and pharmaceutical companies. In *Digital Disruption in Healthcare 2022 Jun 24 [pp. 187-207]. Cham: Springer International Publishing.*
 6. Aagaard L, Strandell J, Melskens L, Petersen PS, Holme Hansen E. Global patterns of adverse drug reactions over a decade: analyzes of spontaneous reports to VigiBase™. *Drug Saf.* 2012 Dec 1;35[12]:1171-82. doi: 10.1007/BF03262002.
 7. Ozcan G, Aykac E, Kasap Y, Nemutlu NT, Sen E, Aydinkarahaliloglu ND. Adverse Drug Reaction Reporting Pattern in Turkey: Analysis of the National Database in the Context of the First Pharmacovigilance Legislation. *Drugs Real World Outcomes.* 2016 Mar;3[1]:33-43. doi: 10.1007/s40801-015-0054-1.
 8. Avong YK, Jatau B, Gurumnaan R, Danat N, Okuma J, Usman I, *et al.* Addressing the under-reporting of adverse drug reactions in public health programs controlling HIV/AIDS, Tuberculosis and Malaria: A prospective cohort study. *PLoS One.* 2018 Aug 22;13[8]:e0200810. doi: 10.1371/journal.pone.0200810.
 9. Hohl CM, Small SS, Peddie D, Badke K, Bailey C, Balka E. Why Clinicians Don't Report Adverse Drug Events: Qualitative Study. *JMIR Public Health Surveill.* 2018 Feb 27;4[1]:e21. doi: 10.2196/publichealth.9282.
 10. Hazell L, Shakir SA. Under-reporting of adverse drug reactions : a systematic review. *Drug Saf.* 2006;29[5]:385-96. doi: 10.2165/00002018-200629050-00003.
 11. Rivkees SA. Primum non nocere [first, not to harm] and secundus, opinio vulnero [second, report the harm]. *Int J Pediatr Endocrinol.* 2009;2009:303509. doi: 10.1155/2009/303509.
 12. Kumar DA, Reddenna L, Basha SA. Pharmacovigilance programme of India.
 13. Kesharwani R, Singh D, Jacob V. Pharmacovigilance: present status and future prospects in India.
 14. Datta S, Sengupta S. An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting in a tertiary care teaching hospital of Sikkim. *Perspect Clin Res.* 2015 Oct-Dec;6[4]:200-6. doi: 10.4103/2229-3485.167096.
 15. Al-Worafi YM. Re: Improving pharmacovigilance in Europe. *BMJ* 2014; 340: c1694
 16. World Health Organization. Pharmacovigilance: ensuring the safe use of medicines. World Health Organization; 2004.
 17. Mahmoud MA, Alsowaida Y, Alshammari T, Khan TM, Alrasheedy A, Hassali MA, Aljadhey H. Community pharmacists' knowledge, behaviors and experiences about adverse drug reaction reporting in Saudi Arabia. *Saudi Pharm J.* 2014 Nov;22[5]:411-8. doi: 10.1016/j.jsps.2013.07.005.
 18. Hardeep, Bajaj JK, Rakesh K. A survey on the knowledge, attitude and the practice of pharmacovigilance among the health care professionals in a teaching hospital in northern India. *J Clin Diagn Res.* 2013 Jan;7[1]:97-9. doi: 10.7860/JCDR/2012/4883.2680.
 19. Rajesh R, Vidyasagar S, Varma DM. An educational intervention to assess knowledge attitude practice of pharmacovigilance among health care professionals in an Indian tertiary care teaching hospital. *Int J Pharm Tech Res.* 2011 Apr;3[2]:678-92.
 20. Fadare JO, Enwere OO, Afolabi AO, Chedi BA, Musa A. Knowledge, attitude and practice of adverse drug reaction reporting among healthcare workers in a tertiary center in Northern Nigeria. *Trop J Pharmaceut Res.* 2011;10[3]:235-242. doi: 10.4314/tjpr.v10i3.4.
 21. Kamtane RA, Jayawardhani V. Knowledge, attitude and perception of physicians towards adverse drug reaction [ADR] reporting: A pharmaco-epidemiological study. *Asian J Pharm Clin Res.* 2012;5[3]:210-4.



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Print ISSN: 2636-4174

Online ISSN: 2682-3780

of Medical Arts