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## Research Article

### Evaluation Of Knowledge, Attitude And Practices Of Pharmacovigilance In Health Care Professionals Of Tertiary Care Teaching Institute In Tribal Region Of Central India

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#### ABSTRACT

**Background:** Adverse Drug Reactions (ADRs) are an important contributor to patient morbidity and hospitalization. Spontaneous reporting of ADRs is an important tool in pharmacovigilance. Under-reporting may increase medicine-induced morbidity and mortality among patients. The success of WHO International Drug Monitoring Programme is entirely dependent on the contributions of National Pharmacovigilance centres. India has a National pharmacovigilance Centre. **Aim and Objectives:** To determine the knowledge, attitude, practices of ADR reporting and factors affecting the reporting. **Material and Methods:** A cross-sectional, questionnaire based study conducted in doctors, nurses and pharmacists of tertiary care teaching institute of tribal region of central India. **Results:** 4.76 % doctors wrote the correct definition of ADR while 58.7% could mention drugs banned due to ADR. Only [7/28 (25%)] nurses had knowledge of banned drugs and none could name any drugs. [5/10 (50%)] pharmacist had knowledge of banned drugs but none could name them. [35/92 (38.88%)] doctors and only one nurse had seen an ADR. Only [20/92 (21.73%)] doctors were having knowledge of Pharmacovigilance Program of India (PvPI), while none of nurses and pharmacists were aware of this. Similarly [46/92 (50%)] of doctor, [14/28 (50%)] nurses, [5/10 (50%)] think that ADR reporting should be professional obligation

**Conclusions:** The knowledge of ADRs was good in doctors, but knowledge of PvPI was poor in all. How to report and time constraints are limiting factors. Participants think that ADR reporting should be a professional obligation. Incentives in the form of up-gradation of services were suggestions given by nurse participants.

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## INTRODUCTION

An adverse drug reaction (ADR) is defined by WHO as “ a noxious , unintended effect of a drug that occurs in dose normally used in humans for the diagnosis , prophylaxis and treatment of disease .”<sup>[1]</sup> The occurrences of ADRs depend on the patient’s age , gender , genetic constitution, diseases condition . ADRs are also common with poly-pharmacy .<sup>[2]</sup> They affect both children and the adults with varying magnitudes , causing both morbidity and mortality.<sup>[3-5]</sup> In addition to human costs, ADRs have a major impact on public health by imposing a considerable economic burden on the society and the already stretched health-care system particularly in developing countries. <sup>[6]</sup> .ADR reporting forms a part of health care, therefore health care professionals world-wide should report on ADRs . Pharmacovigilance is the pharmacological science relating to the collection, detection, assessment, monitoring and prevention of adverse effects or any other drug related problem, mainly long term or short term side effects of pharmaceutical products. <sup>[7]</sup>Pharmacovigilance not only helps in early detection of ADRs, but also facilitates identification of both risk factors and the mechanism underlying the ADR.

The WHO International Drug Monitoring is coordinated by the WHO Collaborating Centre for International Drug Monitoring, known as the Uppsala Monitoring Centre (UMC) in Sweden .The current global network of pharmacovigilance centres, is co-ordinated by UMC as the international database of suspected adverse drug reaction reports from all over the world. <sup>[8]</sup> .The success of UMC is entirely dependent on the contributions of National Pharmacovigilance Centres which have played a significant role in increasing public awareness of drug safety..

India is the fourth largest producer of pharmaceuticals in the world. It is emerging as an important clinical trial hub in the world. Many new drugs are being introduced in India. Therefore, there is a need for a vibrant pharmacovigilance system in the country to protect the population from the potential harm

that may be caused by some of these new drugs. <sup>[9]</sup>In India the ADR reporting is carried out by a National Program called Pharmacovigilance Programme of India(PvPI) which was developed in July 2010. It is a combined initiative by Central Drug Standard Control Organization(CDSCO), New Delhi, Ministry of Health and Family Welfare (MoHFW) , Government of India. In order to strengthen the programme , and for better implementation a National Coordinating Center under Indian Pharmacopoeia Commission (IPC), Ghaziabad, (U.P.) has been developed. <sup>[10]</sup> All academic Medical Institutes in India are the ADR monitoring centres (AMCs). Case-control studies and other pharmaco-epidemiological methods have increasingly been used to estimate the harm associated with medicines once they have been marketed. Academic centers of pharmacology and pharmacy have played an important role through teaching, training research, policy development, clinical research, ethics committees and the clinical services they provide. <sup>[11-13]</sup>.

Although India is participating in the program, its contribution to the UMC is not satisfactory. <sup>[6]</sup> This is basically due to lack of reporting culture among healthcare workers here . Increased reporting of ADRs from each and every country will help in generating a global database and thus strengthening the entire program.The present issue of concern is under reporting of ADRs due to various confounding factors. <sup>[10]</sup> Initially the physicians were the only professionals invited to report as judging whether disease or medicine causes a certain symptom by exercising the skill of differential diagnosis. Today all health care professionals and patients themselves are allowed to observe different kinds of drug related problems and report them directly<sup>[14,15]</sup> Only a patient knows the actual benefit and harm of a medicine taken. Direct patient participation in the reporting of drug related problems also increases the efficiency of the pharmacovigilance system and compensate for some of the inadequacies of

systems based on reports from health professionals only.

The knowledge ,attitude and practice is the best tool to assess ADR reporting among all health care professionals and their perspective towards pharmacovigilance and patients safety. Previous reported studies has found that under-reporting of ADR is rated with shortcomings in the knowledge and attitude among health-care professionals. [2,11,12] Health professional's active participation in the pharmacovigilance programme can improve the ADR reporting<sup>[12]</sup>

#### **AIM AND OBJECTIVES:**

- To determine the knowledge ,attitude, practices(KAP) on spontaneous ADR reporting by health professionals
- To find out factors affecting the reporting process
- To correlate these findings with their professional `characteristics.

#### **MATERIAL AND METHODS:**

##### ***Study design***

This was a cross-sectional, observational, questionnaire-based study conducted in treating doctors(medical officers having first degree qualification and residents doctors , assistant professors, associate professors ,professors ), nurses, dispensing pharmacists of a tertiary care teaching institute of central India from Feb to Aug 2018. A total of 200 health care professional subjects to the inclusion and exclusion criteria were enrolled in the study.

##### ***Design of the questionnaire***

A questionnaire was developed to obtain information on the knowledge attitude ,practices of pharmacovigilance and adverse drug reactions reporting using the precedence set by similar studies<sup>[16,17]</sup> Content validity was assessed by distributing the questionnaire to 10 health care professionals recruited to complete the validation process. The final form of the questionnaire consisted of healthcare professionals demographic data, and a total of 10 open and closed ended questions that can assess respondents knowledge attitude and

practices towards pharmacovigilance and ADRs reporting. Questions related to factors affecting reporting of ADRs reporting were also evaluated. In the last the participants were asked for suggestions /remarks ,if any.

##### ***Data collection procedure***

The healthcare professionals were provided with a copy of the questionnaire after explanation of the objectives of the study. During the survey, the purpose of the study was explained to participants, both verbally and by covering letter which was attached with consent form and ethical clearance. Health care professionals were informed that their participation in the study is voluntary and only those who agreed to participate ,their face to face interview was taken and questionnaire was filled . Those not willing to participate were excluded from the study.Those who were very busy at the moment, questionnaires were left to them and collected after a maximum of two working days. The returned questionnaires were checked for completeness, consistency and clarity before collected. Participants were told that all information provided was completely confidential and the results would be presented anonymously.

##### ***Ethical considerations***

The study received ethical clearance from Institutional ethics committee (ECR/1033/Inst/MH/2018) before the start of the study

##### ***Data treatment and analysis***

All questionnaires were identified by instituting identification number and the questions were coded. The filled questionnaires were analysed as per the objectives of the study based on professional differentiations. The data obtained were entered in Microsoft excel spread sheet and were analysed. Results were expressed in absolute number and percentages.

#### **RESULTS:**

Out of 200 participants only 130 filled their questionnaire, giving the response rate of 65%. Table 1 shows knowledge ,attitude, practices, of ADR reporting amongst the different group of participants. 66(71.7%) doctors and

4(14.29%)nurses have seen ADR during their practice but only 22(23.9%) doctors reported the ADR and none of the nurses reported any ADR. Only 16(17.4%)doctors are technically updated with the PvPI mobile application. Fig 1. shows the distribution of respondents Fig 2 shows sources of drug information in respondents .Textbooks, medical journals, medical representatives, seminars, promotional literature, internet are the different sources of drug information for most of the doctor participants. Medical representatives and promotional literature were cited as important source of information in few nurses. Promotional literature was the only source of information in few pharmacists.Fig 3 shows opinion of respondents regarding who can report ADRs. Most of the participating doctors

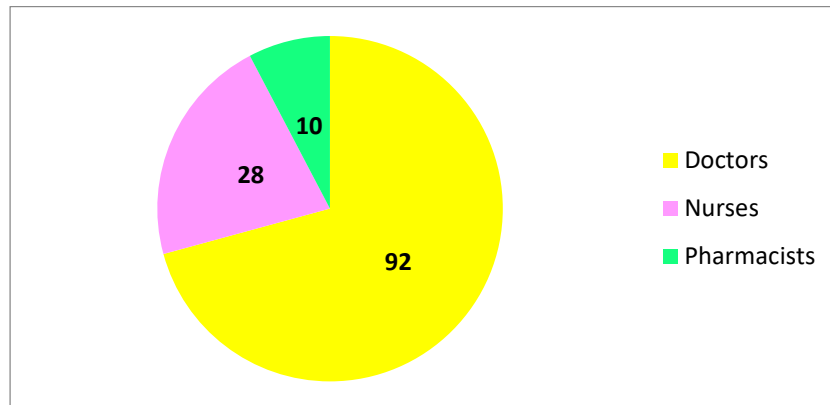
opine that all the health care professionals including the patient themselves can report the ADRs. The knowledge of nurses and pharmacists was poor regarding who can report the ADRs. When asked about banned drugs only the doctor participants could name Nimesulide,Thalidomide, Cisapride , Ibuprofen , Terfenadine as banned drugs. Fig.4 shows factors discouraging respondents from reporting ADRs with lack of time and where to report as major drawbacks . Reporting to be made easy,serious ADRs should be prioritized considering the workload of the prescribers , appointing an ADR specialist were suggestions given by participating doctors. Incentives in the form of service benefits was suggested by nurses and pharmacists.

*Table.1: Knowledge, attitude, practices of ADR reporting among health professionals*

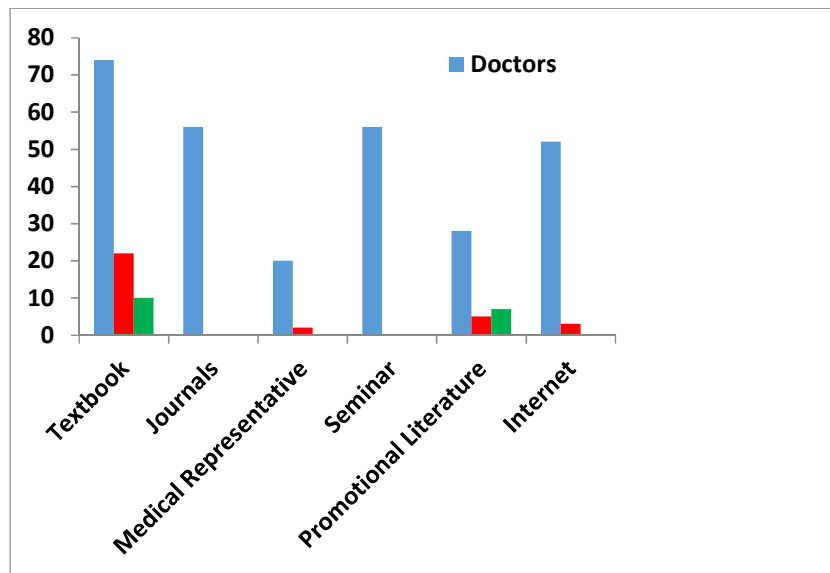
Questions	Doctors n=92 (%)	Nurses n=28 (%)	Pharmacists n=10 (%)
Definition of ADR attempted by	84(91.30)	28(100)	10(100)
Written correct definition of ADR	4(4.76)	none	None
Aware of banned drugs	70(76)	7(25)	5 (50)
Knowing the names drugs which cause ADRs	54(58.7)	none	none
Seen any ADR during practice	66(71.7)	4(14.29)	none
Shared the information of seen ADR	44(47.82)	4(14.28)	none
Knowing about PvPI	40(43.47)	none	none
Knowing about PvPI mobile application	16(17.4)	none	none
Seen ADR reporting form	20(21.73)	none	none
Think that ADR reporting should be taught to them and should be professional obligation	46(50)	14(50)	5(50)

*PvPI: Pharmacovigilance program of India*

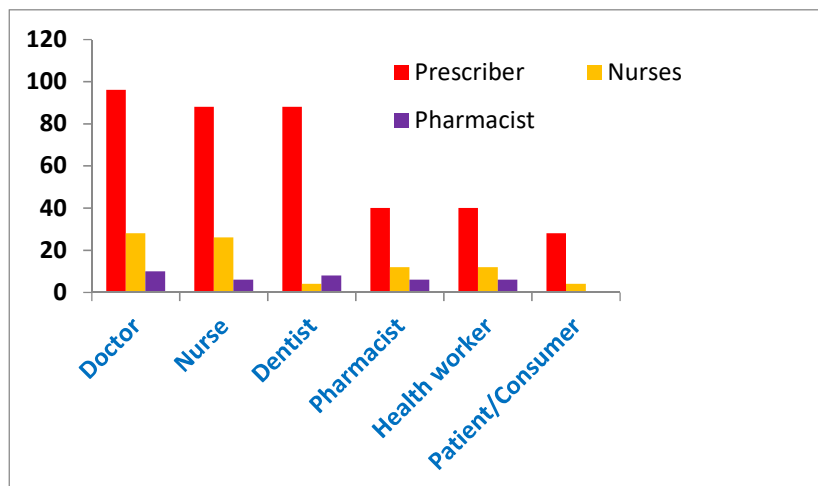
*Fig 1. Shows the distribution of respondents (n=130)*

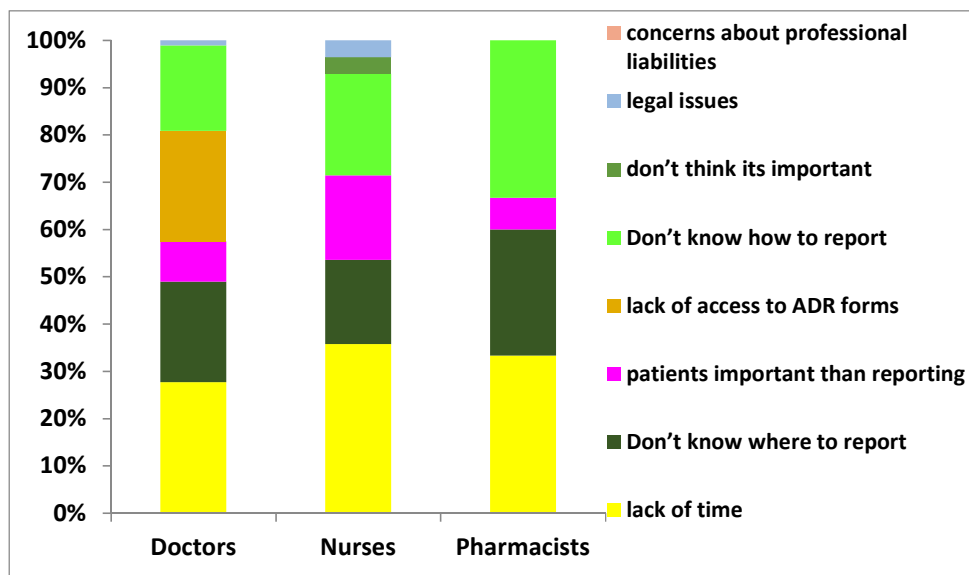


*Fig 2 : Shows sources of drug information in respondents(n=130)*



*Fig 3 .Opinion of respondents regarding who can report ADRs(n=130)*



*Fig.4 : Factors discouraging respondents from reporting ADRs(n=130)*

#### DISCUSSION:

Pharmacovigilance programs have played a major role in detection of ADRs and banning of several drugs from the market. However, underreporting of ADRs is very common. Health professionals are to be sensitized and motivated regarding ADR reporting. We performed a cross sectional questionnaire study to evaluate knowledge, attitude and practices of health professionals about pharmacovigilance and ADR reporting in an academic medical institute of central India. The response rate in the present study was 65% which is corresponding to other studies[18,19]. In the present study about 76% of doctors were aware of banned drugs and 59% could name them while none of the nurses and pharmacists were aware of the same. This may be because of lack of drug information sources for nurses and pharmacists as found in the study. The sources of drug information should be made available to these care takers which will help to update themselves. This can be done by providing library and web facilities in their work place like wards and out patient departments(OPDs).

In the present study many prescriber participants (71.7%) had seen an ADR while 14.29% nurses and none of the pharmacists had ever seen an ADR, while in a study from Nepal

82.7% of doctors, 67.4% of nurses and 65.6% of pharmacists had seen ADR during their routine work<sup>[20]</sup>. This reveals that in our set up only doctors are closely monitoring the patients for ADRs while the paramedical staff though involved directly in patient care is not used to keep watch on ADRs. When asked about knowledge of Pharmacovigilance Programme (PvPI) only 43.47% doctors respondents were aware of it, while none of the nurses or pharmacists were knowing about the same. Similar findings are reported in other studies carried out in India<sup>[19,20]</sup>. As per the requirement of the schedule Y of Drug and Cosmetic Act, Indian Pharmacopoeia Commission (IPC), National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI) under the union health ministry, the PvPI is a part of the skill development programme in India under the government's ambitious Pradhan Mantri Kaushal Vikas Yojana (Prime-Ministers scheme) to produce and encourage qualified pharmacovigilance personnel which includes doctors, nurses, pharmacists for effective pharmacovigilance. Proper implementation of this scheme will sensitize the health workers towards ADR reporting, generating the database also controlling morbidity and mortality due to ADRs.

Likewise among all health professionals participants of our study few doctors(23.7%) had seen an ADR reporting form. This might be due to inadequate promotion of reporting form and reporting system . The awareness program should focus on the filling method of the ADRs form and the details of the reporting procedure. Ours is referral hospital converted to new teaching institute with the present scenario .Another motivational step of the government of India is expanding health care system by converting district(referral ) hospitals to teaching care hospitals where one of the feature is compulsory ADR monitoring centre. ADR reporting will be taught to undergraduate and postgraduate students along with creating awareness about ADR monitoring and reporting among health care professionals and consumers, through appropriate educational interventions like seminars, Continued Medical Educations (CMEs), make ADR reporting forms easily available and simplifying the process of ADR reporting through android application . In this way we expect expansion of PvPI to a considerable high level and thus improvement in ADR reporting

The IPC - NCC for PvPI, has developed an advanced version of the android mobile application (app),named by “ADR PvPI” which can be downloaded free and empowers all the healthcare professionals and consumers for ADR reporting. Through this app, related images of ADR and lab investigation reports can be attached in a user-friendly manner for clinical assessment and signal detection . In the present study we had seen the knowledge and practices of health professionals of the ADR PvPI application. Few doctor participants(17%) were aware about it ,while none of the nurses and pharmacists are knowing about this app. In today’s era when the technology is at every door step with easy availability and accessibility ,the ADR PvPI mobile app makes the task of ADR reporting easy and time saving, can be utilised by all health care professionals as well as patients to upload the ADRs This will definitely upsurge the reporting

of ADRs , hence increasing the awareness and utility of this app is the need of the hour.

Regarding who can report the ADRs , in the present study the doctor participants were of the opinion that all health care professionals including the consumers can report the ADRs while the same was inadequate in case of pharmacists and nurses who thought that only doctors can report ADRs .Similar findings are reported in other studies<sup>[19,20]</sup>.When the care takers will be aware of their role in reporting of ADRs then only they will be more attentive for monitoring of patients for ADRs.

Among the various factors discouraging respondents from reporting ADRs lack of time and where to report were the major drawbacks in our study. The main reasons for under reporting of ADRs in other studies were lack of time, poor knowledge on the reporting mechanisms, and unfamiliarity with the existence of national pharmacovigilance system, belief that the ADR was already well known, and doubt about the importance of the ADRs reporting and fear to report ADRs<sup>[22,23,24]</sup> Reporting to be made easy,serious ADRs should be prioritized considering the workload of the prescribers , appointment of a technical staff for reporting ADRs were suggestions given by participating doctors. Incentives in the form of up-gradation of services were suggested by nurses.

#### CONCLUSIONS:

In the present study, KAP for ADR reporting existed among doctors and lack in nurses and pharmacists ,but the reporting culture in doctors was less due to time constraints . CMEs , workshops , training programmes sensitizing the medical and paramedical staff for ADR reporting will be helpful. Use of the PvPI mobile app for reporting will definitely make the task easier and time saving. Suggested measures by the participants could improve the quantum and quality of the reports. Amplifying the reporter base by extending it to nurses, pharmacists, and other health care professionals would definately help strengthen ADR reporting which is a part of health care.

**SPECIAL MENTION**

This paper was presented by **Aishwarya Rathod** a 2<sup>nd</sup> M.B.B.S student at Government Medical College ,Gondia, Maharashtra, India. The paper won 4<sup>th</sup> place and Rs 10000 as prize in Oral presentation in **International Research Competition 2018** at AAPI GLOBAL HEALTH CARE SUMMIT 2018 held at Mumbai in Dec 2018.Certificate attached as Annexure.

**REFERENCES**

- 1) World Health Organisation, "International Drug Monitoring: the role of national centres," Technical Report Series 498, World Health Organization, Geneva, Switzerland, 1972.
- 2) W. N . Mulatu , A. Worku , "Assessment of knowledge , attitude and practice of health professionals towards adverse drug reaction reporting and factors associated with reporting ," Journal of Pharmacovigilance, vol.2 no.4 , 2014
- 3) C. George , et al. "Reporting adverse drug reactions: a guide for healthcare professionals," BMA Board of Science ,2006.
- 4) T. Kurokawa, et al. Safety Monitoring of Medicinal Products :Guidelines for Setting up and Running a Pharmacovigilance Centre. The Uppsala Monitoring Centre ( UMC) , WHO Collaborating Centre for International Drug Monitoring , 2000.
- 5) A. R. Abubakar et al "A systemic review of knowledge , attitude and practice of adverse drug reactions and pharmacovigilance among doctors," Journal of Applied Pharmaceutical Science, vol. 4,no. 10 , pp. 117-127 , 2014.
- 6) Oshikoya KA , Awobusuyi JO . Perceptions of doctors to adverse drug reaction reporting in a teaching hospital in Lagos , Nigeria .BMC ClinPharmacol 2009;9:14.
- 7) World Health Organization. The Importance of Pharmacovigilance-Safety Monitoring of Medicinal Products.Geneva:World Health Organization. 2002.
- 8) Jayanthi C.R.. " An observational study to analyze the Adverse Drug Reaction among the Elderly at A Tertiary Care Hospital". Biomedical and Pharmacology Journal.2017;10(1):345-52
- 9) Pharmacovigilance Programme of India(PvPI)[homepage on the internet].The start of Programme.Updated on Jan 30, Available from: [http://www.ipc.gov.in/PvPI/pv\\_home.html](http://www.ipc.gov.in/PvPI/pv_home.html) .
- 10) Hazell L.,Shakir S.A. Under-reporting of adverse drug reations. Drug Safety.2006;29(5):385-96.
- 11) Ganesan S., Vikneswaran G., Reddy K. C et al. A Survey on Knowledge ,Attitude and Practice of Pharmacovigilance towards Adverse Drug Reactions reporting among Doctors and Nurses in a Tertiary Care Hospital in South India.J Young Pharm. 2016;8(4):471-6.
- 12) Desai C.K.,Iyer G.et al. An evaluation of knowledge ,attitude and practices of adverse drug reaction reporting among prescribers at a tertiary care hospital. Perspectives in Clinical research.2011;2(4):129.
- 13) Gupta S.K, Nayak R.P et al. A questionnaire study on the knowledge ,attitude and practice of pharmacovigilance among the health care professionals in a teaching hospital in South India.Perspectives in clinical research.2015;6(1):45.
- 14) Khan S.A, Goyal C, et al. Knowledge , attitude and practice of doctors to adverse drug reaction reporting in a teaching hospital in India: An observational study. J Nat Sci Biol Med.2013;4:191-6.
- 15) Muraraiah S., Rajarathna K, et al. A questionnaire study to assess the knowledge , attitude and practice of Pharmacovigilance in a Paediatric tertiary care centre . J Chem Pharm Res.2011;3:416-22.

- 16) Subish P, Izham MM.et.al. Evaluation of the knowledge, attitude and practices on adverse drug reactions and pharmacovigilance among healthcare professionals in a Nepalese hospital: A preliminary study. *Internet J Pharmacol.* 2008;6:1.
- 17) Ramesh M, Parthasarathi G.et al. Adverse drug reactions reporting: attitudes and perceptions of medical practitioners. *Asian J Pharm Clin Res.* 2009;2:10–4.
- 18) Ghosh S, Ali S, Chhabra Let al. Investigation of attitudes and perception of medical practitioners on adverse drug reaction reporting – a pilot study. *T Ph Res.* 2010;3:1–9.
- 19) Shyam Kumar Damodar, Jitto Joseph et.al.Assessment of Knowledge, Awareness and Practices among Healthcare Professionals about Pharmacovigilance and Adverse Drug Reactions Reporting in Dharmapuri and Krishnagiri Districts of Tamilnadu, India *Journal of Pharmacy Practice and Community Medicine.*2018, 4(1):33-38
- 20) Santosh KC , Pramote Tragulpiankit et al. Attitudes among healthcare professionals to the reporting of adverse drug reactions in Nepal. *BMC Pharmacology and Toxicology* 2013, 14(16):1-7
- 21) Harsha Ramakrishnaiah et al. A comparative study of adverse drug reactions reported by healthcare professionals and patients in a tertiary care teaching hospital .*IJBCP International Journal of Basic & Clinical Pharmacology* 2017 May;6(5):1078-1084
- 22) Hardeep JK, Rakesh Kumar. A Survey on the Knowledge, Attitude and the Practice of Pharmacovigilance Among the Health Care Professionals in a Teaching Hospital in Northern India. *JCDR.* 2013;7(1):97-99.
- 23) Lateef M, Khan A et.al.Adverse drug reactions in hospitalized pediatric patients of Saudi Arabian University Hospital and impact of pharmacovigilance in reporting ADR. *Saudi Pharm J.* 2013;21(3):261-6.
- 24) Okechukwu RC, Odinduka SO.et al. Awareness, Attitude, and Practice of Pharmacovigilance among Health Care Professionals in Nigeria: Survey in a Teaching Hospital, *Int J Hospital Res.* 2013;2(3):99-108

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