


**ORIGINAL ARTICLE****KNOWLEDGE, ATTITUDE AND PRACTICE OF INTERNS REGARDING PHARMACOVIGILANCE IN A TERTIARY HOSPITAL OF MADHYA PRADESH**Prashant Wadagbalkar<sup>1</sup>, Vikalp Tiwari<sup>2</sup>, Swati Raipurkar<sup>3</sup><sup>1</sup>Professor, Dept of Pharmacology, RKDF Medical College & Research Center Bhopal, <sup>2</sup>Assistant Professor, Dept of Pharmacology, MGM Medical College & Research Center, Indore, <sup>3</sup> Dept of Paediatrics, Index Medical College Hospital and Research Centre, Indore**ABSTRACT:**

Background: One of the global problems encountered these days affecting majority of both children and adults causing both morbidity and mortality and which are also a major impact on public health are Adverse drug reactions (ADRs) are global problems and affects majority both children and adults causing both morbidity and mortality and also a major impact on public health. Hence; we planned this study to assess the knowledge, attitude and practice of interns regarding pharmacovigilance in a hospital of Madhya Pradesh. **Material & methods:** The present study was conducted in the tertiary hospital of Madhya Pradesh and included assessment of knowledge, attitude and practice of interns regarding pharmacovigilance in a hospital of Madhya Pradesh. The questionnaire was made to evaluate the Knowledge Attitude Practice (KAP) of pharmacovigilance among the interns. The questionnaires were distributed among the interns to fill up the answers and 30 min of time duration was given for fill up the answer. All the results were analyzed by SPSSs software. **Results:** The KAP questionnaire consisted of total 23 questions. Out of which 10 related with knowledge, 8 related with attitude and 5 related with practice of pharmacovigilance. Correct definition of Pharmacovigilance was given by 35.8 percent of the interns while exact purpose of Pharmacovigilance was known to 45.2 percent of the interns. 54.2 percent of the interns knew that detailed teaching of the pharmacovigilance to health professionals is necessary. 51.2 percent of the subjects encountered adverse drug reaction in the patients during internship training programme. **Conclusion:** Inadequate knowledge among interns regarding pharmacovigilance.

**Key words:** Drug reactions, Pharmacovigilance

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**INTRODUCTION**

One of the global problems encountered these days affecting majority of both children and adults causing both morbidity and mortality and which are also a major impact on public health are Adverse drug reactions (ADRs) are global problems and affects majority both children and adults causing both morbidity and mortality and also a major impact on public health.<sup>1, 2</sup> The success of a pharmacovigilance program depends upon the active involvement of the healthcare professionals such as doctors, pharmacist, nurses. Being the key healthcare professionals, providing information on suspected ADRs is as much a moral duty for the Doctor as other aspects of patient care. Spontaneous ADR reporting is important to monitor known and unknown adverse effects of medicines.<sup>3, 4</sup> Furthermore, spontaneous reporting of ADRs has played a most important role in the detection of serious and unusual ADRs during marketing of the drug in actual practicing in the market. This has led to the withdrawal

of many drugs in the past such as rofecoxib, cisapride, terfenadine, etc.<sup>5</sup> To transform the pharmacovigilance activity into practices for enhancing the safety of patient and more ADR monitoring center are being set up across the country under pharmacovigilance program of India (PvPI).<sup>6, 7</sup> Hence; we planned this study to assess the knowledge, attitude and practice of interns regarding pharmacovigilance in a tertiary hospital of Madhya Pradesh.

**MATERIALS & METHODS**

The present study was conducted in the tertiary hospital of Madhya Pradesh and included assessment of knowledge, attitude and practice of interns regarding pharmacovigilance in the tertiary hospital of Madhya Pradesh. It was a cross sectional, observational, questionnaire based study. The study was conducted at tertiary hospital of Madhya Pradesh. Ethical approval was taken from institutional ethical committee and written consent was obtained after explaining in detail

the entire research protocol. The study was conducted among 80 interns who had completed at least 9 months of their internship programme. The questionnaire was made to evaluate the Knowledge Attitude Practice (KAP) of pharmacovigilance among the interns. The KAP questionnaire was obtained from the previous studies.<sup>7-9</sup> The questionnaires were distributed among the interns to fill up the answers and 30 min of time duration was given for fill up the answer. Any clarification needed in understanding the questionnaires and additional time to filled form was provided. Those Interns students who were busy at that moment was requested to return back the duly filled form within 1-week. The KAP survey questionnaire was analyzed, question-wise and their percentage value was calculated with the help of Microsoft excel spread sheet in MS Office 2007. All the results were analyzed by SPSSs software. Chi-square test was used for the assessment of level of significance.

## RESULTS

The KAP questionnaire consisted of total 23 questions. Out of which 10 related with knowledge, 8 related

with attitude and 5 related with practice of pharmacovigilance.

### Knowledge related questions

Correct definition of Pharmacovigilance was given by 35.8 percent of the interns while exact purpose of Pharmacovigilance was known to 45.2 percent of the interns. 34.5 percent of the interns were aware of the parameters included in Pharmacovigilance whereas 27.7 percent of the interns knew about the location of the international centre of ADR.

### Attitude related questions

89.5 percent of the subjects thought it to be necessary to report about the ADR to the concerned authority. 54.2 percent of the interns knew that detailed teaching of the pharmacovigilance to health professionals is necessary.

### Practice related questions

51.2 percent of the subjects encountered adverse drug reaction in the patients during internship training programme while 3.1 percent of the individuals reported ADR to pharmacovigilance centre. 35.3 percent of the individuals have seen the ADR reporting form.

**Table 1:** Questionnaires used for assessment of knowledge of pharmacovigilance

S No	Questions	Percentage of correct response
1.	Pharmacovigilance: Definition	35.8
2.	Pharmacovigilance: Purpose	45.2
3.	Pharmacovigilance includes?	34.5
4.	Location of international centre of ADR	27.7
5.	Indian regulatory body of ADR	52.4
6.	Rare ADR usually identified in which phase of clinical trial	27.9
7.	Types of ADR according to Wills and Brown	40.8
8.	Common type of ADR	24.1
9.	Order of ADR submission	34.2
10.	Indian chairman of pharmacovigilance programme	37.3

**Table 2:** Questionnaires used for assessment of attitude of pharmacovigilance

S No	Questions	Percentage of correct response
1.	Reporting of adverse drug reaction is necessary?	89.5
2.	Detail teaching of pharmacovigilance to health professionals?	54.2
3.	Have you read any article about adverse drug reaction	46.9
4.	ADR monitoring centre in all the hospitals is necessary?	47.1
5.	Reporting of case of to health professional by a nonmedical person is allowed?	62.7
6.	Do you think reporting of an adverse drug reaction is obligation to you	39.3
7.	Your knowledge regarding the existence of National pharmacovigilance programme in India.	33.8
8.	Your awareness about the term pharmacovigilance	85.1

**Table 3:** Questionnaires used for assessment of practice of pharmacovigilance

S No	Questions	Percentage of correct response
1.	You encountered adverse drug reaction in the patients during internship training programme	51.2
2.	Have you ever reported ADR to pharmacovigilance centre?	3.1
3.	Have you ever seen the ADR reporting form?	35.3
4.	You received training on the reporting of adverse drug reaction	18.6
5.	In your institute, is any pharmacovigilance committee present?	22.8

## DISCUSSION

World Health Organization (WHO) has defined Pharmacovigilance as the "science and activities relating to the detection, assessment, understanding and prevention of the adverse effects (AE)", particularly long term and short term side effects of medicines or any other drug related problems.<sup>8-10</sup> This plays a vital role in ensuring that the doctors together with the patients are provided with adequate safety information to make an educated decision when choosing a drug for treatment.<sup>11</sup> Notwithstanding the constant endeavor by the Pharmacovigilance Programme of India towards inculcating a culture of ADR monitoring; underreporting is still very prevalent. There is a requirement for constant training and enactment of regulations for ADR reporting among healthcare professionals. Previous reported study has found that underreporting of ADR is related with shortcomings in the knowledge and attitude among healthcare professionals.<sup>12</sup> Hence; we planned this study to assess the knowledge, attitude and practice of interns regarding pharmacovigilance in a tertiary hospital of Madhya Pradesh.

In the present study, we observed inadequate awareness about pharmacovigilance among interns. Approximately 30% interns answered correctly about knowledge related questions of pharmacovigilance. Good pharmacovigilance knowledge is very important for practicing pharmacovigilance. Less than 20 percent of the interns had knowledge about 'how to report ADR?'. Gupta et al evaluated the knowledge, attitude, and practices (KAP) of the healthcare professionals about pharmacovigilance in Perambalur (Tamil Nadu), a tertiary care teaching hospital. The second primary objective was to assess the causation of underreporting of adverse drug reactions (ADRs) as it needs to be well-assessed in India. The secondary objective was to compare the findings of this study with the results of the published studies from India on evaluation of the KAP of pharmacovigilance among healthcare professional. A cross-sectional study was carried out using a pretested questionnaire. The questionnaire was designed to assess the KAP regarding pharmacovigilance. The healthcare professionals (doctors, nurses, and pharmacists) working in the DSMCH, Perambalur (Tamil Nadu) during the study period were included. Only those who gave their consent to participate were included in the study. 69.3% healthcare professional agreed that ADR reporting is a professional obligation for them. Among the participants, 64.4% have experienced ADRs in patients, but only 22.8% have ever reported ADR to pharmacovigilance center. Unfortunately only 53.5% healthcare workers have been trained for reporting adverse reactions. But, 97% healthcare professionals agreed that reporting of ADR is necessary and 92.1% were of the view that pharmacovigilance should be taught in detail to healthcare professional. This study demonstrated that knowledge and attitude towards pharmacovigilance is gradually improving among healthcare professionals, but unfortunately the actual practice of ADR reporting is still deficient among them.<sup>13</sup> Upadhyaya et al evaluated the

knowledge, attitude and practices (KAP) toward pharmacovigilance and ADRs of postgraduate students of their institute. A cross-sectional questionnaires based study was carried out in postgraduate students of the clinical department at a tertiary care hospital, Vadodara, Gujarat (India). A total of 22 questionnaires about KAP toward ADRs and pharmacovigilance were developed and peer viewed of all questionnaires by expert faculties from the institute. They were contacted directly to postgraduate students of respective clinical department; questionnaires were distributed and taken back after 30 min. Only 7.92% of postgraduate doctors were reported ADR at institute or ADR reporting center. It concluded that postgraduate students have a better attitude toward reporting ADRs, but have lack of knowledge and poor practices of ADRs. The majority of postgraduate students were felt ADR reporting and monitoring is very important, but few had ever reported ADRs because of lack of sensitization and knowledge of pharmacovigilance and ADR.<sup>14</sup> Toklu et al investigated the knowledge and attitudes of community pharmacists towards pharmacovigilance and adverse drug reactions (ADRs) in Kadiköy district of Istanbul (Turkey). The questionnaire consisted of questions about the sociodemographic characteristics of the pharmacists, their knowledge of pharmacovigilance and their attitudes towards ADR reporting. The knowledge of pharmacovigilance practice, ADR reporting compliance rates, reasons for not reporting ADR and perceptions of the Turkish community pharmacists on pharmacovigilance practice were evaluated. Although all 411 pharmacies in the Kadikoy district were visited, only 53% of the community pharmacists (n = 219) consented to participate in the study. Of those that did respond, only 17.2% of the pharmacists had any knowledge about 'pharmacovigilance'. Sixty-five percent of the pharmacists stated that patients reported an ADR to them during the previous 12 months, and 21% of pharmacists reported to the concerned organizations. Our survey showed that only 7% actually reported an ADR to the national pharmacovigilance center. On the other hand, 89% of the pharmacists believed that the role of the pharmacist in ADR reporting was essential. The results showed that Turkish community pharmacists have poor knowledge about pharmacovigilance. There is an urgent need for educational programs to train them about pharmacovigilance and ADR reporting.<sup>15</sup>

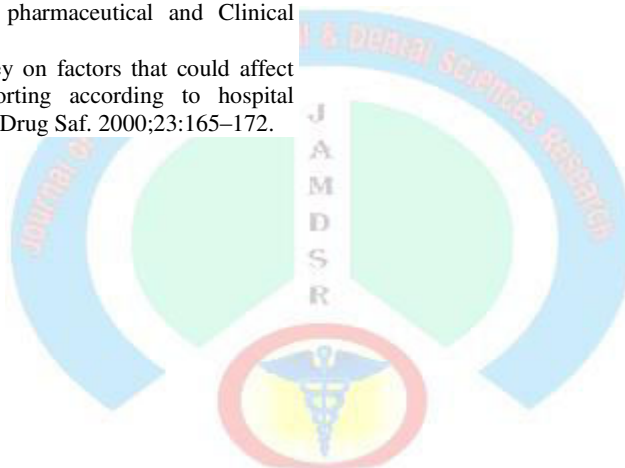
## CONCLUSION

From the above results, the authors concluded that inadequate knowledge among interns regarding pharmacovigilance. Hence, it is recommended that regular educational programs should be carried to increase awareness among interns regarding this area of pharmacology.

## REFERENCES

1. Vallano A, Cereza G, Pedròs C, Agustí A, Danés I, Aguilera C, Arnau JM. Obstacles and solutions for spontaneous reporting of adverse drug reactions in the hospital. *Br J Clin Pharmacol.* 2005;60:653–658.

2. www.Pharmacovigilance.co.in (Accessed on December. 2011)
3. The Learning Centre Continuing pharmacy education; fall 1999. Canada: University of British Columbia; 1999. Pharmacists are number one.
4. Bäckström M, Mjörndal T, Dahlqvist R, Nordkvist-Olsson T. Attitudes of reporting adverse drug reactions in Northern Sweden. *Eur J Clin Pharmacol.* 2000;56:729–732.
5. Amrita P, Roomi MT. Scenario of Pharmacovigilance and ADR Reporting among Pharmacists in Delhi. *Indian Journal of Pharmacy Practice.* 2011;4:29–38.
6. Oreagba IA, Ogunleye OJ, Olayemi SO. The knowledge, perceptions and practice of Pharmacovigilance amongst community pharmacists in Lagos state, south west Nigeria. *Pharmacoepidemiol Drug Saf.* 2011;20:30–35.
7. Green CF, Mottram DR, Raval D, Proudlove C, Randall C. Community pharmacists' attitude to adverse drug reaction reporting. *Int J Pharm Pract.* 1999;7:92–99.
8. Fadare JO, Enwere OO, Afolabi AO, Chedi BAZ, Musa A. Knowledge, Attitude and Practice of Adverse Drug Reaction Reporting among Healthcare Workers in a Tertiary Centre in Northern Nigeria. *Trop J Pharm Res.* 2011;10:235–242.
9. Madhan R, Parthasarathi G. Attitudes and perceptions of medical practitioners-Adverse drug reactions reporting. *Asian Journal of pharmaceutical and Clinical Research.* 2009;2:184–189.
10. Sweis D, Wong IC. A survey on factors that could affect adverse drug reaction reporting according to hospital pharmacists in Great Britain. *Drug Saf.* 2000;23:165–172.
11. Gupta P, Udupa A. Adverse Drug Reaction Reporting and Pharmacovigilance: Knowledge, Attitudes and Perceptions amongst Resident Doctors. *J Pharm Sci Res.* 2011;3:1064–1069.
12. Eland IA, Belton KJ, van Grootheest AC, Meiners AP, Rawlins MD, Stricker BH. Attitudinal survey of voluntary reporting of adverse drug reactions. *Br J Clin Pharmacol.* 1999;48:623–627.
13. Green CF, Mottram DR, Brown AM, Rowe PH. Attitudes of hospital pharmacists to adverse drug reactions and the 'yellow card' scheme: A qualitative study. *Int J Pharm Pract.* 1999;7:247–55.
14. Amrita P, Kharbanda B. Knowledge, attitude and skills of nurses of Delhi towards adverse drug reaction reporting. *Indian J Pharm Pract.* 2012;5:45–51.
15. Ramesh M, Pandit J, Parthasarathi G. Adverse drug reactions in a south Indian hospital – Their severity and cost involved. *Pharmacoepidemiol Drug Saf.* 2003;12:687–92.



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