Observational Study

Evaluation of awareness and practice of pharmacovigilance among medical practitioners

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The recent launch of National Pharmacovigilance program which is still in infancy. In India, problem is under-reporting of ADRs. This study was aimed at investigating the knowledge, attitude and awareness about ADR reporting among doctors in teaching hospital, practitioners and third year MBBS students. The survey questionnaires were distributed to three groups of medical practitioners and MBBS students. 1st group (n=36) includes clinicians and post graduates in medical college. 2nd group (n=30) includes private practitioners. 3rd group (n=40) includes IIIrd year MBBS students. In 83.3% institutional clinicians, 86.6% private practitioners and 80% students were aware of Pharmacovigilance and ADR monitoring system. ADR reporting was practiced by 0% institutional and 13.3% private practitioners, (p<0.05). 83.4% institutional doctors, 70% private practitioners and 75% students were not aware of spontaneous reporting. 72.2% institutional doctors, 56.6% private practitioners and 37.5 students said direct ADR reporting by patients should not be allowed (p<0.001), 67% institutional doctors, 57% private practitioners and 80% students said Pharmacists should be involved in ADR reporting. In 17% institutional doctors, 47% private practitioners and 15% students had knowledge of causality assessment, (p<0.001). Thus there is dire need of creating awareness for ADR reporting among practicing doctors and post graduates who are future doctors. Awareness of Pharmacovigilance and activities related to this should be included in undergraduate syllabus. The effective Pharmacovigilance and ADR reporting in India is possible only if training of all health professionals is done effectively and made mandatory by MCI. [*J Indian Med Assoc* 2019; **117:** 15-7]

Key words **: Pharmacovigilance, ADR monitoring, Spontaneous reporting system.**

Drug safety monitoring is an essential element for the effective use of medicines and for high quality medical care. India a population of over 1.22 billion has vast ethnic variability, different disease prevalence patterns, parallel practices of different systems of medicines and different socioeconomic status. Adverse drug reactions (ADRs) are global problems of major concern, which may lead to increase morbidity and mortality[1,2]. It also has a major impact on public health by imposing a considerable economic burden on the society and the already stretched health care systems[3]. Hence it is important to have standardized and robust Pharmacovigilance and safety monitoring program for the nation. By definition Pharmacovigilance is, "The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems". Pharmacovigilance is an important and integral part of clinical research, both clinical trial safety and post-marketing. Pharmacovigilance is one of the important post-marketing tools in ensuring the safety of pharmaceutical and related health products.

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Since 1978 the Programme has been carried out by the Uppsala Monitoring Centre (UMC) in Sweden. The Uppsala Monitoring Centre is responsible for the collection of data about adverse drug reactions from around the world, especially from countries that are members of the WHO including India. In India the Ministry of Health & Family Welfare has initiated the Pharmacovigilance Programme of India (PvPI) which is co-ordinated by the Central Drugs Standard Control Organization (CDSCO). The programme is coordinated by the Indian Pharmacopeia commission, Ghaziabad as a National Coordinating Centre (NCC). Under this programme there are different ADR monitoring centers(AMCs), asked to work cohesively to improve ADR reporting in India.

The recently launched national Pharmacovigilance program which is still in infancy. In India, problem is under-reporting of ADRs[4,5], due to many factors like financial incentives, rewards for reporting, legal aspects, lack of ADR related knowledge and attitudes. It is estimated that only 6–10% of all ADRs are reported[6]. This high rate of under-reporting can delay signal detection and consequently impart negatively on the public health. Post marketing surveillance of drugs is very important in analyzing and managing the risks associated with drugs, once they

are available for the use of the general population. Spontaneous reporting has contributed significantly to successful Pharmacovigilance in U.K by using yellow card system.

The contribution of health professionals, in this regard to ADRs databases is enormously significant and has encouraged ongoing ascertainment of the benefit-risk ratio of drugs[7,8]. Pharmacovigilance programme in India would be successful only through a coordination and dedicated effort of health care professionals. This study was therefore aimed at investigating the knowledge, attitudes and awareness of doctors towards ADR reporting in a teaching hospital, practicing doctors and third year MBBS students and to suggest possible ways of improving spontaneous reporting based on our findings.

Materials and Methods

Study setting Questionnaire based cross-sectional study after approval from IEC, conducted in D.Y Patil medical college Kolhapur, Maharashtra. 106 medical professionals including consultants, residents, final year MBBS students in teaching hospital, and private practitioners, were included in the study. The doctors who were not willing to participate in the study and the ones who were on leave were excluded.

Methodology

The survey questionnaire with 10 questions were distributed to three groups ie, Group 1 (n=36) included clinicians and post graduates working in medical college. Group 2 (n=30) included private practitioners and Group 3 (n=40) includes IIIrd year MBBS students. The questionnaire was adapted from the previous studies and improvised by peer discussion . The questions were structured to obtain the information about the knowledge, attitude, awareness towards Pharmacovigilance and ADR reporting practice and factors influencing this attitude. Provision was also made for suggestions on possible ways to improve ADR reporting.

Initially the workshop on Pharmacovigilance was conducted in the medical college. The questionnaires were distributed through the various Heads of Departments in hospital, third year medical students and private clinicians, allowed to stay with them for 4 weeks so as to allow them enough time to attend to the questions. While retrieving the questionnaire the same copy was re-administered to those who could not produce the previous copy given to them. This is to encourage non-respondents to participate in the study. Questionnaires were collected and analyzed question wise and there percentage values were calculated. Statistical analysis was done by applying "chi square test".

Observations and Results

As given in table 83.3% institutional clinicians, 86.6% private practitioners and 80% students were aware of Pharmacovigilance and ADR monitoring system. ADR reporting was practiced by 0% institutional and 13.3% private practitioners. Thus Significant difference was seen in these two groups ($p<0.05$) (Table 1). 75% students said they were sufficiently made aware about ADR reporting. 83.4% institutional doctors,70% private practitioners and 75% students were not aware of spontaneous reporting. 72.2% institutional doctors, 56.6% private practitioners and 37.5% students said direct ADR reporting by patients should not be allowed. Thus highly significant difference was seen in these three groups ($p<0.001$). 67% institutional doctors, 57% private practitioners and 80% students said pharmacists should be involved in ADR reporting. In 17% institutional doctors, 47% private practitioners and 15% students had knowledge of causality assessment. Thus highly significant difference was seen in these three groups ($p<0.001$). All three groups said, this system is going to benefit the patients and they wanted to know more about this system.

Discussion

The present study evaluated the knowledge, attitude and practice of Pharmacovigilance in healthcare professionals. Over all they are aware about Pharmacovigilance system held in India, but do not know how it actually works and where to report ADRs.

Pharmacovigilance programs have played a major role in detection of ADRs of drugs from the market[9]. However, under reporting of ADRs is one of the major problems associated with pharmacovigilance programs. In our study we found none of institutional doctor has reported any of the ADRs. Few ADRs were reported by private practitioners. Thus it is very important to bring awareness of ADR reporting among them as they are frontier level healthcare professionals, who are actually going to report ADRs.

A study from Northern India reported that the knowledge, attitude and practice regarding ADR monitoring among students and prescribers was comparable but need further improvement[10]. A study from Italy reported that doctors had little information concerning ADRs and ADR reporting systems[11].In our study we identified that there is awareness about Pharmacovigilance program, but actual ADR reporting was very low among the doctors. This finding suggests need for improvement and sensitization of

Table 1 — *Showing Pharmacovigilance and ADR monitoring system and others*

	Institutional clinicians	Private practitioners	IIIrd MBBS Students	'p' value
Awareness of Pharmacovigilance & ADR monitoring system	83.3%	86.6%	80%	0.76
Awareness of ADR reporting	83.4%	70%	75%	0.43
ADRs reported	0%	13.3%	Question not included	0.03*
Awareness of spontaneous reporting	83.4%	70%	75%	0.43**
ADR reporting by patients not recommended	72.2%	56.6%	37.5%	0.096
Pharmacists involvement	67%	57%	80%	0.055
Knowledge of causality assessment	17%	47%	15%	0.0039**

*Significant ($p<0.05$)
**Highly significant ($p<0.001$) by applying chi square test.

the healthcare professionals to report ADRs. In our study many suggestions were given by doctors, like, Simple ADR filling form, A toll free phone number to report, ADR, Feedback should be given, keeping drop box in hospital, awards to boost, frequent workshops and CMEs to be arranged on ADR reporting and Pharmacoviglance.

Conclusion

Awareness of Pharmacovigilance system has been increased, but actual ADR reporting is lacking. Thus there is dire need of creating awareness for ADR reporting among practicing doctors and post graduates who are future doctors. Awareness of Pharmacovigilance and activities related to this should be included in undergraduate syllabus. The effective Pharmacovigilance and ADR reporting in India is possible only if training of all health professionals is done effectively and made mandatory by MCI.

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