AWARENESS OF PHARMACOVIGILANCE AMONG DOCTORS INCLUDING POSTGRADUATE STUDENTS IN A TEACHING HOSPITAL

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ABSTRACT

Aims & Objectives : To study the awareness of pharmacovigilance among doctors and postgraduate students in a tertiary care institution and to evaluate the knowledge and attitude of doctors and postgraduate students to adverse drug reaction reporting.

Materials & Methods: 107 doctors including postgraduates working in Vinayaka Mission Medical College Hospital, Karaikal were evaluated with a questionnaire for their knowledge and attitudes to ADR reporting. The questionnaire sought the demographics of the doctors, their knowledge and attitudes to ADR reporting, the factors that they perceived may influence ADR reporting, and their levels of education and training on ADR reporting. Provision was also made for suggestions on the possible ways to improve ADR reporting.

Results : 37% of respondents considered doctors as the ideal health professionals to report ADRs. Only 2.8% of the respondents knew about the existence of Regional Pharmacovigilance Centre (RPC) at JIPMER,Poncicherry. 15.9% respondents were aware of the 'Suspected ADR reporting form' but only 1.9% had ever reported ADRs to the RPC. 22.4% of respondents felt that ADR reporting should be made compulsory for it to be effective. Education and training was the most recognised means of improving ADR reporting.

Conclusion : The knowledge of ADRs is adequate but attitude towards reporting ADR is not satisfactory mainly due to lack of awareness about the reporting form and Pharmovigilance centres. More awareness should be created on the 'Suspected ADR reporting form' .Continuing medical education, training and integration of ADR reporting into the clinical activities of the doctors would likely improve reporting.

Key words: *ADR-adverse drug reaction, Pharmacovigilance, RPC-regional pharmacovigilance centre, Suspected ADR reporting form.*

BACKGROUND

The World Health Organisation defines Pharmacovigilance[1] as "the pharmacological science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems".

Pharmacovigilance plays an important role in ensuring safety of drugs. Though the efficacy and adverse effects of drug is screened by doing clinical trials(phases 1-3), post marketing surveillance(phase 4) is mandatory to identify the serious cum rare adverse effects of established drugs and adverse effects of newer drugs.

Pharmacovigilance is concerned with the post marketing surveillance of medicines and the use of the information generated for education and effective drug regulation. Pharmacovigilance plays an important role in the rational use of medicines by providing information about Adverse drug reactions (ADRs)[2] in the general population. An adverse drug reaction is a 'response to a medicine which is noxious and unintended, and which occurs at doses normally used in man'. Adverse drug reactions are global problems of major concern. They affect both children and adults with varying magnitudes, causing both morbidity and mortality[3,4,5,6]. Knowledge of the adverse effects of drugs is important for effective treatment. Communicating the potential harm of drug-use to patients is a matter of high priority and should be carried out by every prescriber. It is estimated that only 6–10% of all ADRs are reported[7].

In India, there is a National Pharmacovigilance centre at New Delhi which is regulated by Central Drug Standard Control Organization(CDSCO).There are five regional centres including South Regional Pharmacovigilance centre at Jipmer, Pondicherry.

Adverse drug reaction reporting should be done by all health care professionals including doctors, nurses and pharmacists and they have to fill up the Suspected ADR Reporting Form voluntarily provided by pharmacovigilance centres. Information provided in this

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form is handled in strict confidence. Peripheral Pharmacovigilance Centres will forward this form to the Regional PharmacovigilanceCentres, where the causality analysis is carried out and the information is forwarded to the Zonal Pharmacovigilance Centres. Finally the data is statistically analysed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Center in Sweden.

OBJECTIVES

1. To study the awareness of pharmacovigilance among doctors and postgraduate students
2. To evaluate the knowledge and attitude of doctors and postgraduate students to ADR reporting
3. To suggest the ways to improve ADR reporting among doctors and postgraduate students

MATERIALS & METHODS

This is a cross sectional study conducted in 107 doctors including postgraduates in Vinayaka Missions Medical College Hospitals, karaikal, a tertiary care centre. Professionals who are not willing to participate were excluded from the study. The participants were asked to fill a questionnaire8 which includes the demographics of the doctors, their knowledge and attitudes to ADR reporting, the factors that they perceived may influence ADR reporting, and their levels of education and training on ADR reporting. Provision was also made for suggestions on the possible ways to improve ADR reporting. Any doubts regarding the understanding and filling of the questionnaire were clarified. The collected data were analysed.

RESULTS

Questionnaires were distributed to 110 doctors including postgraduates, and 107 responded giving a response rate of 97.2%. The non-respondents were not interested in participating in the study.

The demographic profile of the respondents is given in Table.1

Character	**Value**
Mean age (years)	31
Male : Female ratio	62 : 45
Cadre	
Faculty	44 (41.1%)
Post graduates	63 (58.9%)
Place of undergraduate education	
Tamilnadu	49 (45.8%)
South india	37 (34.6%)
North india	12 (11.2%)
Abroad	9 (8.4%)

Out of 107 respondents 58.9% were postgraduates and most of the respondents had their undergraduate education from South India.

Question		**Number**	**Percentage**
Existence of RPC[+](SOUTH)	Aware	74	69.2%
	Not aware	33	30.8%
Location of RPC Office	Aware	3	2.8%
	Not aware	104	97.2%
Existence of 'Suspected ADR Reporting Form'	Aware	17	15.9%
	Not aware	90	84.1%
Submitted ADR Reporting form to RPC	Yes	2	1.9%
	No	105	98.1%
All ADRs should be reported for newly marketed agents	Yes	107	100%
	No	0	-
Serious ADRs should be reported for established products	Yes	107	100%
	No	0	-
Professionals eligible to report ADR	Only doctors	37	34.6%
	Doctors, Nurses, Pharmacist, patients	16	14.9%

*Adverse drug reaction , † Regional Pharmacovigilance Centre

Table 2 shows that 74 (69.2%) of respondents are aware of the existence of Regional Pharmacovigilance Centre(South),but only 3(2.8%) respondents knew the actual location of the RPC Office at JIPMER,Pondicherry.100% of the respondents agreed that all ADRs should be reported for newly marketed drugs, and that only serious ADRs should be reported for established products.37(34.6%) of the respondents have the idea that only doctors can report ADR, whereas 16 (14.9%) have the idea doctors,nurses, pharmacists,physiotherapists,patients can report ADR.

Table 3

Factors that may discourage doctors from reporting adverse drug reaction

Factor	Number/ Percentage
Concern that the report may be wrong	7(6.5%)
Lack of time to fill in a report and opinion that a single unreported case may not affect ADR* database	43(40.2%)
Level of clinical knowledge makes it difficult to decide whether or not an ADR has occurred	3(2.8%)
Lack of time to actively look for an ADR while at work	7(6.5%)
Don't feel the need to report well recognized actions	0
The absence of fee for reporting	29(27.1%)
Concern that a report will generate an extra work	2(1.9%)
Fear of the negative impact the report may have on the company that produced or marketed the drug	7(6.5%)
Lack of confidence in discussing the ADR with other colleagues	9(8.4%)

*Adverse Drug Reaction

Among the factors that may discourage ADR reporting, 43 (40.2%) respondents quoted Lack of time to fill in a report and opinion that a single unreported case may not affect ADR database, as the discouraging factor.29 (27.1%) respondents quoted the absence of financial incentives as the factor that discourages reporting.

Table 4

Proportion of respondents who would report hypothetical cases of ADR*s

Reaction	Yes	No	Don't know
Jaundice with frusemide	43(40.2%)	39(36.4%)	25(23.4%)
Skin rashes with Azithromycin	54(50.5%)	29(27.1%)	24(22.4%)
Headache with Isosorbide dinitrate	31(29%)	63(58.8%)	13(12.2%)
Cough with Enalapril	29(27.1%)	64(59.8%)	14(13.1%)
Thrombocytopeni a with Heparin	73(68.2%)	30(28%)	4(3.8%)
Gastrointestinal bleed with Diclofenac	84(78.5%)	18(16.8%)	5(4.7%)

*Adverse Drug Reactions

From the list of hypothetical cases of ADRs illustrated to the respondents, only four examples listed in Table 4 were considered reportable to the RPC. Gastrointestinal bleed with Diclofenac(78.5%) and Thrombocytopenia with Heparin(68.2%) were more likely to be reported. Headache with Isosorbide dinitrate would also be reported by 29%

Table 5

Suggested methods of improving ADRs* reporting

Methods	Frequency	Percentage
Continuing Medical Education	94	87.9%
Training programmes	56	52.3%
More publicity about reporting scheme in local journals	69	64.5%
Having a ADR specialist in each hospital	18	16.8%

Encouraging online or telephone reporting	37	34.6%
Remuneration for every reported case of ADR	14	13.2%
Leaving an ADR form in ward itself	10	9.3%

*Adverse Drug Reactions

The various methods suggested by the respondents to improve ADR reporting are presented in Table 5. Continuing medical education(87.9%), More publicity about reporting scheme in local journals(64.5%) were the methods mostly recommended. Training Programmes and encouraging online reporting were the other methods favoured to improve reporting of ADRs.

DISCUSSION

The present study evaluated the awareness of doctors and postgraduates regarding ADR reporting and the knowledge about ADRs. Post marketing surveillance(phase 4 clinical trial) of drugs will not be effective unless ADR reporting system is strictly followed. Studies have documented high level of underreporting even in developed countries like United kingdom[9] Italy[10] and France[11]where pharmacovigilance programmes are well established. Studies conducted in teaching institutions in Nigeria and Nepal[12] have also shown poor levels of awareness about ADR reporting schemes.

Our study results show that the professional capability of identifying ADRs is satisfactory, but the attitude towards reporting ADRs is not good. 43(40.2%) of the respondents felt that their act of not reporting a case of ADR is not going to affect the database of ADRs. Also the awareness about the procedure to be followed for reporting ADRs, and about the centre for reporting ADRs is poor. Only 3 (2.8%) respondents knew the actual location of the reporting centre of RPC (SOUTH) at Jipmer,Pondy. Active steps should be taken to improve this situation. This must start at the undergraduate student level onwards[13]. Including Pharmacovigilance in the curriculum, provide training in filling ADR reporting forms during internship will help to some extent. 94(87.9%) respondents felt that Continuing Medical Education will motivate better reporting. Educational intervention has been shown to improve ADR reporting in Portugal14 and Rhode Island in the USA. Further studies should be done to include private practioners and other health professionals so that awareness programmes can be formulated on a larger scale. Pharmacologists play an important role in conducting pharmacovigilance programmes inorder to sensitise clinicians.

CONCLUSION

This study shows that the knowledge of ADRs is adequate but attitude towards reporting ADR is not satisfactory. This is mainly due to lack of awareness about the reporting form and Pharmovigilance centres. More awareness should be created on the 'Suspected ADR reporting form'. Continuing medical education, training and integration of ADR reporting into the clinical activities of the doctors would likely improve reporting. Also Pharmacovigilance can be included as a part of the curriculum for undergraduates inorder to improve ADR reporting once they start medical service.

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