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AWARENESS, ATTITUDE AND PRACTICE OF PHARMACOVIGILANCE AMONG HEALTHCARE PROFESSIONALS AND STUDENTS IN A TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

Aims: To find out the level of awareness & attitude towards pharmacovigilance and extent of ADR reporting in healthcare professionals & medical students.

Materials & method: A total of 799 participants including healthcare professionals and students were asked to fill a predesigned questionnaire. It consisted of questions regarding awareness, attitude & practice of pharmacovigilance. Data collected were analyzed using relevant statistical tests. Awareness between healthcare professionals & students was compared using chi square test.

Results: 70.46% of participants responded to the questionnaire. 22% of doctors and 37% of nurses had reported ADR to any authority in last 2 years. Lack of awareness about the ADR reporting system was the most common reason for non-reporting. Majority of healthcare professionals and students considered ADR reporting as very important and recommended active involvement of pharmacovigilance in medical curriculum. **Conclusion:** Overall level of awareness was low both among healthcare professionals and students. There is a great need to increase the awareness and improve the attitude of healthcare professionals and students towards pharmacovigilance and its national programme. Regular training sessions and awareness campaigns need to be conducted. Pharmacovigilance should be included in the undergraduate training of MBBS, pharmacy, nursing and physiotherapy students.

Keywords: ADR reporting, healthcare professionals, medical students, Pharmacovigilance

INTRODUCTION

Pharmacovigilance as described by WHO is detection, assessment, understanding and prevention of adverse effects or any other drug related problem.[1] Adverse drug reactions (ADRs) are associated with significant morbidity and mortality, and are an important cause of hospitalizations.[2] Studies have shown ADRs as fourth major cause of death in USA, but such data are lacking in India.[3] As health care professionals are the first one who are in contact

with patients taking drugs, spontaneous reporting by them is an effective way to generate early signals of ADRs. It is the most practical way to detect rare adverse events, adverse events caused by prolonged use of drugs and many drug-drug interactions. [4] Thus, awareness among healthcare workers and their attitude towards pharmacovigilance are important determinants of ADR reporting rate.

WHO has developed a system for reporting of ADRs by establishment of International Drug

Monitoring Programme, coordinated by Uppsala Monitoring Centre, Sweden. In India also National Pharmacovigilance Programme (NPP) was started in 2004.[5] This programme was relaunched in 2010 as Pharmacovigilance Programme of India (PvPI), and is now coordinated by the Indian Pharmacopoeia Commission, Ghaziabad.[6] Still pharmacovigilance is in its infancy phase in India and under reporting is a major problem. Studies done in other countries also reveal under reporting of ADRs.[7-10] Lack of awareness among health care professionals is one of the reasons for under reporting. Thus, to improve the ADR reporting rate, it is important to improve the awareness, attitude and practices of the healthcare professionals regarding pharmacovigilance. The best time to do this is during undergraduate training of students of MBBS, pharmacy and nursing. This will help by developing a culture of ADR reporting in healthcare workers. Though studies reporting the level of awareness & practices of pharmacovigilance have been done in other countries, [7, 8, 11, 12] very few studies have focused this aspect in India, and during literature search no such study was found from Rajasthan. Further most of the studies have included healthcare workers, but studies on awareness among undergraduate students are limited. [9] Moreover, there was no peripheral centre of NPP in Rajasthan. Recently a new ADR Monitoring Center under PvPI has been established in a Medical College of Rajasthan. [6] Hence, the present study was conducted to develop a baseline data of awareness, attitude and practice of pharmacovigilance in health care professionals and medical students in a Tertiary Healthcare Teaching Hospital in Rajasthan.

MATERIAL AND METHODS

This was a cross sectional, observational, questionnaire based study conducted in a Tertiary Care Teaching Hospital of Rajasthan. Duration of

study was of 2 months from 1st May 2011 to 30th June 2011. Total 799 participants were approached, which included health care professionals and medical students. All healthcare professionals working in the Hospital including clinicians, pharmacists and nursing staff were included. Medical students of MBBS, students of Nursing College, Pharmacy College and Physiotherapy College attached to the Hospital were included in the study. All those who denied participation in the study and students who have not been introduced to Pharmacology (e.g. students who were in 1st year of their course) were excluded from the study.

Procedure:

Approval from Institutional Ethics Committee was taken before starting the study. All health care professionals and students were contacted personally. The study was explained to them in brief. A predesigned questionnaire was provided to them which consisted of ten questions for assessment of awareness, attitude and practice of pharmacovigilance and ADR reporting. Consent of participants was taken in written informed consent form. They were asked to fill the questionnaire without any assistance. It required approximately 10 to 15 minutes filling the questionnaire.

Out of total 799 participants who were asked to fill the questionnaire, 565 (70.7%) responded to the questionnaire. There were 11 pharmacists, only 2 responded. Therefore, pharmacists were not included for analysis. Thus total 563 questionnaires were analyzed. All questionnaires were completely filled. Data collected were analyzed and percentages were calculated. Awareness between healthcare professionals and students was compared using chi square test. Practice of ADR reporting and reasons for non-reporting were assessed only for healthcare professionals as Pharmacovigilance Programme of India (PvPI) mentions only healthcare professionals who can report the ADR. [6]

RESULTS AND DISCUSSION

Among healthcare professionals, 73% (73/100) doctors and 57% (115/202) nurses responded to the questionnaire. Among students, 72.4% (210/290) MBBS students, 96% (100/104) pharmacy students, 61% (33/54) nursing students and 84.2% (32/38) physiotherapy students responded to the questionnaire. 65.4% of healthcare professionals (83.5% of doctors and 53.9% of nurses), while 83.5% of students have ever heard of the term "Pharmacovigilance". (Table 1) Awareness about this term was different between the two groups with statistical significance (p value < 0.001). 41.5% of healthcare professionals (58.9% of doctors and 30.43% of nurses) and 39% of students were able to define Pharmacovigilance. (Table 2) No statistically significant difference between the two groups (p value > 0.005) was found. 39.4% of healthcare professionals (43.8% of doctors and 36.5% of nurses) and 31.7% of students were aware of National Programme for Pharmacovigilance, (Table 2) with no statistically significant difference (p value > 0.005). 53.7% of healthcare professionals (60.3% of doctors and 49.6% of nurses) and 57.1% of students had the knowledge of ADR reporting. (Table 2) No statistically significant difference (p value > 0.005) was found. The awareness that any healthcare professional can report ADR was present in 43.1% of healthcare professionals (67.1% of doctors and 27.8% of nurses) and 48.3% of students, (Table 2) with no statistically significant difference (p value > 0.005). 72.3% of healthcare professionals (91.8% of doctors and 60% of nurses) and 60.8% of students were aware how to report ADR. (Table 2) There was statistically significant difference between two groups with p value < 0.01 . 78.1% of doctors and

62.6% of nursing staff have not reported any ADR to any authority in last two years. Only 21.9% of doctors and 37.4% of nursing staff have reported any ADR to any authority in last two years. (Figure 1)

About 56% of doctors and 46% of nurses reported lack of awareness about the reporting system as the major cause of non-reporting of ADR. 20.5% of doctors and 23.5% of nurses were not sure about the reason for non-reporting. (Table 3) 68% of healthcare professionals (75% of doctors and 63% of nurses) and 76.8% of students opined that ADR reporting is very important. Only 2.6% of healthcare professionals and 1.6% of students considered it as waste of time. (Figure 2) 84% of healthcare professionals (97% of doctors and 75.6% of nurses) and 84.3% of students accepted that pharmacovigilance should be an active part of medical curriculum. Only 5.8% of healthcare professionals and 6.4% of students denied. (Figure 3)

The overall awareness about pharmacovigilance and ADR reporting was low, both in healthcare professionals and students. Though majority of students (83.5%) had heard the term "Pharmacovigilance", less than half (39%) could define it. These students are told about it in pharmacology but not actively discussed. This shows that there is a need to stress on pharmacovigilance during undergraduate teaching. On the other hand 65% of healthcare professionals had heard this term which is significantly lower than that of students, but only 41% could define it. More doctors (59%) were able to define than nursing staff (30%). Healthcare professionals are not exposed to pharmacology after II year of undergraduate course, which may be responsible for their low awareness about the term "Pharmacovigilance". A Nigerian study done on community pharmacists also reported similar results in which 55% of responders were aware of

the term “pharmacovigilance”, but only 18% could define it. [8]

More alarming was the lack of awareness about the national programme. More than half of healthcare professionals and students were not aware about the national programme which is running since 2004 in India. If they do not know about it, how could they be expected to participate in it? To make the national programme successful, it is important to aware the healthcare professionals about it and how it functions. This can be done by awareness campaigns, information leaflets etc.

About half of healthcare professionals (54%) and students (57%) were aware about ADR reporting. The awareness that every healthcare professional including doctor, nurse, pharmacist and physiotherapist can report ADR was very low, which is in accordance with the findings of Gupta P et al.[13] This awareness was minimum among nurses, both nursing staff (28%) as well as nursing students (21%). Active involvement of paramedical staff in spontaneous reporting is very important, since they are in close contact with the patients and for a longer duration as compared to doctors.

The ultimate goal of Pharmacovigilance is that the benefits of medicine use outweighs the risks and thus safeguard the health of patients. Spontaneous ADR reporting by healthcare professionals can play an important role to achieve this goal. In present study only about 22% of doctors and 37% of nurses had reported ADR to any authority in last two years. Other studies have also reported such low levels of ADR reporting. [7-9] Under-reporting is a major and worldwide problem associated with spontaneous reporting system. A systematic review by Hazell L et al has stated significant and widespread under-reporting of ADRs to spontaneous reporting systems including serious or severe ADRs. [10] Aggressive interventions are required to encourage the

healthcare professionals for ADR reporting. They need to be informed that why ADR reporting is necessary and how it can help in ensuring safe and rational use of medicines. Prescribers can be encouraged by providing feedback on their ADR reports, discussion on ADR reports in academic meetings and publishing bulletins on ADRs. Oreagba et al have suggested that remuneration for ADR reporting may increase the reporting rate. [8] Lack of awareness about the reporting system was the most common reason stated by responders (56% of doctors & 46% of nurses) for non-reporting. This finding is in accordance with that reported by other studies, [8, 9, 13] and is understandable as there is no well established reporting system in this hospital and healthcare professionals are not well aware about the national programme. Thus to improve the reporting rate, ADR monitoring centers should be established in all healthcare institutions, at least at tertiary care level. The recent Pharmacovigilance Programme of India targets to establish such centre in most of the Medical Colleges of India in coming years. [6] This may help to improve the existing scenario. Further to increase the awareness about ADR reporting system, regular training sessions and awareness campaigns should be conducted which may help in improving ADR reporting rate. Ramesh M et al have reported 63% increase in ADR reporting in one year after the launch of continuous awareness campaign. [14] As mentioned by other studies lack of time, complex procedure and non significant ADR, were among the other reasons for non-reporting in present study also. [8, 13]

Both healthcare professionals and students had positive attitude toward ADR reporting and majority of them considered it as very important. Only 2.6% of healthcare professionals and 1.6% of students considered it as waste of time. Further majority of responders (84%) opined that pharmacovigilance should be taught as an active

part of medical curriculum. As medical students are future healthcare professionals, there is a need to actively train them, so that pharmacovigilance becomes a part of their medical practice. As recommended by Rehan et al knowledge and awareness of pharmacovigilance among prescribers can be improved by a reinforcement training programme at the commencement of internship and thereafter through continuous education programmes. [9]

The major limitation of the present study is that the study findings could not be applied to wider medical community as the study was restricted to hospital setup. Therefore it is recommended that several studies of similar kind especially in community setup need to be conducted to know the awareness and attitude of healthcare professionals in community and their practice of pharmacovigilance. This will help to find out the present status and to develop strategies to improve the ADR reporting system in India.

CONCLUSION

The results of present study show lack of awareness about pharmacovigilance in healthcare professionals and students. ADR reporting rate is also very low among healthcare professionals. There is a great need to create awareness and promote ADR reporting among healthcare professionals. Regular training sessions to stress the importance of ADR reporting and the functioning of reporting system are required. Further awareness about the national programme need to be increased, this will ensure greater participation from healthcare professionals and success of such programmes. Pharmacovigilance should be a part of undergraduate curriculum of not only MBBS students but also of students of nursing, physiotherapy and pharmacy. As these students are future healthcare professionals, this will help in developing a culture of ADR reporting in the country.

Table No. 1: Frequency of responders who ever heard the term “Pharmacovigilance”

S. No.	Group	Subgroup (n)	Ever heard ‘Pharmacovigilance’	Percentage
1.	Healthcare	Doctors (73)	61	83.56
	Professionals	Nurses (115)	62	53.9
2.	Students	MBBS (210)	198	94.28
		Nursing (33)	19	57.57
		Pharmacy (100)	68	68
		Physiotherapy (32)	28	87.5

Table No. 2: Level of awareness about Pharmacovigilance and ADR reporting

S. No.	Awareness	Healthcare Professionals (%)		Students (%)			
		Doctors (n=73)	Nurses (n=115)	MBBS (n=210)	Nursing (n=33)	Pharmacy (n=100)	Physiotherapy (n=32)
1.	What is Pharmacovigilance	58.9	30.4	48.6	18.2	23	46.9
2.	National Programme	43.8	36.5	31.4	27.3	35	28.1
3.	ADR Reporting	60.3	49.6	59	42.4	56	62.5
4.	Who can report	67.1	27.8	60.5	21.2	33	43.7
5.	How to report ADR	91.8	60	63.3	36.4	63	62.5

Table No. 3: Reasons for non-reporting of ADRs

S. No.	Reasons	Healthcare Professionals (%)	
		Doctors (n=73)	Nurses (n=115)
1.	Lack of awareness	56.2	46.1
2.	Lack of time	8.2	8.7
3.	Complex procedure	8.2	9.5
4.	No significance	6.9	12.2
5.	Not sure	20.5	23.5

Figure No. 1: Frequency of ADR reported by Healthcare Professionals in last 2 years

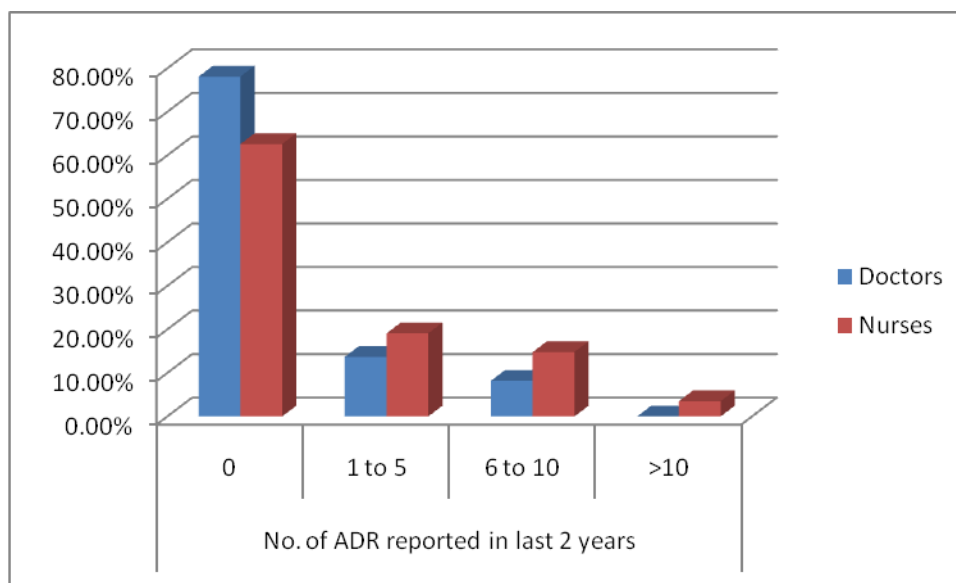


Figure No. 2: Importance of ADR reporting in views of Healthcare Professionals & Students

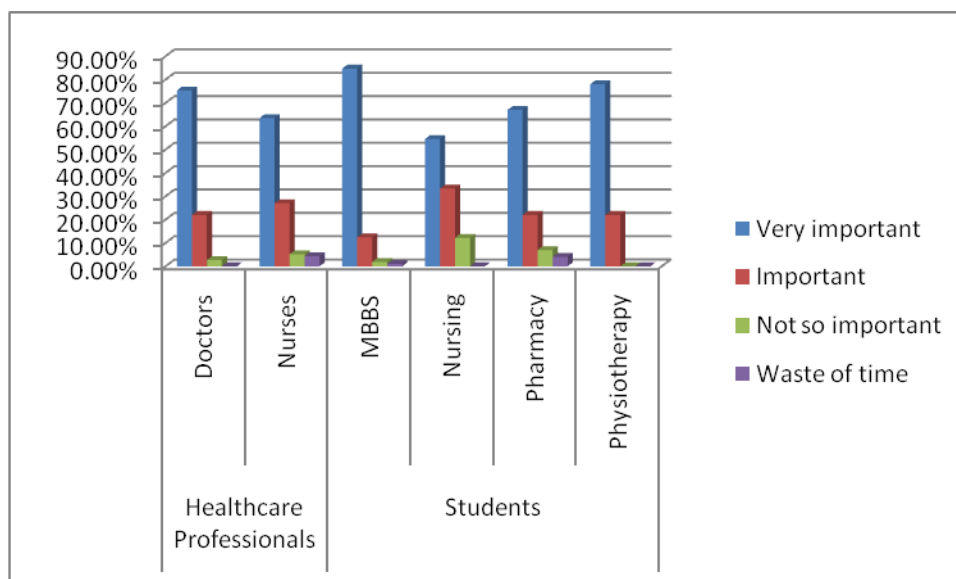
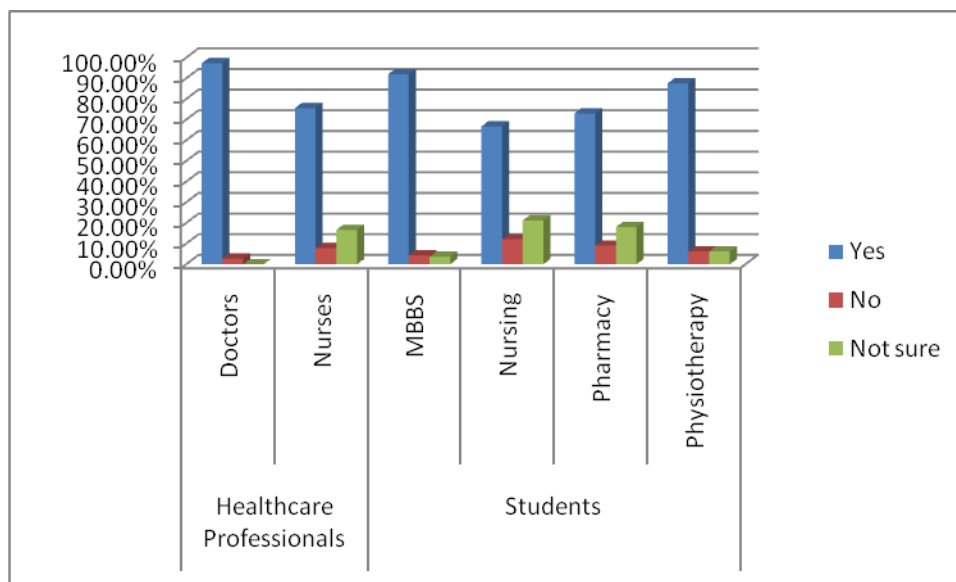


Figure No. 3: Opinion of responders regarding inclusion of Pharmacovigilance in medical curriculum



REFERENCES

1. Tripathi KD. Essentials of medical pharmacology. 6th ed. New Delhi: Jaypee Brothers Medical Publishers (P) Ltd; 2010. p. 79.
2. Classen DC, Pestonik SL, Evans RS, Lloyd JF, Burke JP. Adverse drug events in hospitalized patients. JAMA 1997;277(4):301-6.
3. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients – a meta-analysis of prospective studies. JAMA 1998;279:1200-5.
4. Oates JA. The science of drug therapy. In: Brunton LL, editor. Goodman & Gilman's the pharmacological basis of therapeutics. 11th ed. New York: McGraw-Hill; 2006. p. 133-5.
5. List of NPP centers [Online]. [2010?] [cited 2011 Jan 22]; Available from: URL:<http://www.pharmacovigilance.co.in/nppcentreslist.html>
6. Pharmacovigilance programme of India for assuring drug safety. Central drug standard control organization, Directorate General of health services, Ministry of health and family welfare, Government of India [Online]. [cited 2011 Aug 8]; Available from: URL: <http://cdsco.nic.in/pharmacovigilance.htm>
7. Subish P, Mohammed Izham MI, Mishra P. Evaluation of the knowledge, attitude and practice on adverse drug reactions and pharmacovigilance among healthcare professionals in a Nepalese hospital: a preliminary study. The Internet Journal of Pharmacology 2008;6(1).
8. 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;20:30-5.
9. Rehan HS, Vasudev K, Tripathi CD. Adverse drug reaction monitoring: knowledge, attitude and practices of students and prescribers. *Natl Med J India* 2002;15:24-6.
 10. Hazell L, Shakir SA. Under-reporting of adverse drug reactions : a systematic review. *Drug Saf* 2006;29(5):385-96.
 11. Xu H, Wang Y, Liu N. A hospital-based survey of healthcare professionals in the awareness of pharmacovigilance. *Pharmacoepidemiol Drug Saf* 2009 Jul;18(7):624-30.
 12. Ohaju-Obodo JO, Iribhogbe OI. Extent of pharmacovigilance among resident doctors in Edo and Lagos state of Nigeria. *Pharmacoepidemiol Drug Saf* 2010;19(2):191-5.
 13. Gupta P, Udupa A. Adverse drug reaction and pharmacovigilance: knowledge, attitude and perceptions amongst resident doctors. *J Pharm Sci & Res* 2011;3(2):1064-9.
 14. Ramesh M, Parthasarathi G. Adverse drug reactions reporting: attitude and perceptions of medical practitioners. *Asian J Pharm Clin Res* 2009;2(2):10-4.