

Evaluation of Knowledge, Attitude and Practice of Pharmacovigilance among Healthcare Professionals

Aman Sharma¹, Rekha Rani², Sanjeev Gupta³, Surbhi Mahajan⁴

^{1,3}Assistant Professor, Department of Pharmacology, GMC Rajouri, India

^{2,4}Demonstrator, Department of Pharmacology, GMC Rajouri, India

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Corresponding author: Dr Surbhi Mahajan

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Abstract

Background: The pharmacovigilance programme of India is aimed at inculcating a culture of ADR reporting and monitoring as underreporting is still very prevalent. The present study was conducted to assess knowledge, attitude and practice of pharmacovigilance among healthcare professionals.

Materials and Methods: 140 healthcare professionals including Doctors, nurses, and pharmacists of both genders were subjected to KAP questionnaire (17 questions) wherein 8 were related to knowledge, 4 related to attitude, and 5 related to practice. These questions were designed based on earlier studies for assessing KAP of ADR reporting.

Results: 70% correctly defined pharmacovigilance, 81% replied correct regarding role of pharmacovigilance, 74% correctly answered regarding which healthcare professionals are responsible for ADR reporting, only 30% knew how to and where to report an ADR and 25% knew how to fill an ADR form. 78% had correct idea regarding pharmacovigilance programme of India and 48% replied correctly regarding which body is responsible for monitoring ADR's in India, 92% consider ADR reporting as a professional obligation. 60% had witnessed an ADR, 54% had been trained regarding how to report an ADR, 28% had reported ADRs to monitoring centre, and only 15% had actually filled an ADR form.

Conclusion: Though health care professionals had fair degree of knowledge regarding pharmacovigilance and are positive regarding ADR reporting but practice of ADR reporting is found to be deficient among health care professionals.

Key words: ADR Reporting, Pharmacovigilance, Health Care Professionals

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Introduction

Several new drugs are brought into the market everyday; however, the safety of medicines remains to be a major concern for various population groups due to inadequate knowledge [1]. According to the World Health Organization (WHO), an adverse drug reaction (ADR) is any deleterious, inadvertent and

unwanted reaction to drugs when used for prevention, diagnosis, or treatment purposes at therapeutic doses or for modification of physiological function which precludes accidental or deliberate overdose or drug maladministration [2]. The pharmacovigilance programme of India is aimed at promoting a

culture of ADR monitoring as underreporting is still very prevalent. There is a requirement for constant training and enactment of regulations for ADR reporting among healthcare professionals. Previous studies had found that underreporting of ADR's is mainly related to shortcomings in the knowledge and attitude among healthcare professionals regarding Pharmacovigilance [3]. All ADR's ranging from minor to severe reactions should be reported with special concern for ADR's to new drugs, serious adverse drug reactions, unexpected reactions, and drug interactions which are potentially serious or clinically significant. In addition, uncertainty of the causal relationship between the drug and ADR should not be a reason for not reporting [4]. The present study was conducted to assess knowledge, attitude and practice of pharmacovigilance among healthcare professionals.

Results

Table 1: Distribution of subjects

Professionals	Male	Female	P value
Doctors	24	36	0.08
Pharmacists	18	20	0.94
Nursing staff	14	28	0.07
Total	56	84	

Table I shows that among doctors, there were 21 males and 36 females, among pharmacists, 18 were male and 20 females and among nursing staff were 14 males and 28 females. The difference was not significant ($P > 0.05$).

Table 2: Evaluation of knowledge

Questionnaire	Correct answer	Incorrect answer	P value
What is Pharmacovigilance?	70%	30%	0.03
What is role of Pharmacovigilance?	81%	19%	0.02
Where is International Center for Pharmacovigilance located?	72%	28%	0.02
Which healthcare professionals are responsible for ADR reporting?	74%	26%	0.01
Have you any idea regarding Pharmacovigilance programme of India?	78%	22%	0.01
Which body is responsible for monitoring ADR's in India?	48%	52%	0.15
Do you know how to and where to report an ADR?	30%	70%	0.02
Do you know how to fill an ADR form?	25%	75%	0.015

Materials & Methods

The present study comprised of 140 healthcare professionals including Doctors, nurses, and pharmacists of both genders. All were informed regarding the study and their informed consent was obtained. The study was conducted at Department of Pharmacology, GMC Rajouri.

Data such as name, age, gender etc. was recorded. All were subjected to KAP questionnaire (17 questions) wherein 6 were related to knowledge, 4 related to attitude, and 8 related to practice. The questionnaire was structured in Pharmacology department and questions were designed to assess KAP of Pharmacovigilance and ADR reporting among them. Results of the study were subjected to statistical analysis. P value < 0.05 was considered significant.

Table II shows that 70% correctly defined pharmacovigilance, 81% replied correct regarding role of pharmacovigilance, 74% correctly answered regarding which healthcare professionals are responsible for ADR reporting, 78% had correct idea regarding pharmacovigilance programme of India and 48% replied correctly regarding which body is responsible for monitoring ADR's in India. Only 30% knew how to and where to report an ADR and 25% knew how to fill an ADR form. The difference was significant ($P < 0.05$).

Table 3: Assessment of attitude

Questionnaire	Yes	No	P value
Pharmacovigilance programme should be taught in detail?	82%	18%	0.04
Is ADR reporting a professional obligation?	92%	8%	0.01
Is ADR monitoring form complex to fill?	93%	7%	0.02
What is your opinion about opening of maximum number of ADR monitoring centre?	73%	27%	0.05

Table III shows that 82% replied that pharmacovigilance programme should be taught in detail, 92% consider ADR reporting to be a professional obligation, 93% believe that ADR reporting form is complex to fill and 73% were positive regarding opening of maximum number of ADR monitoring centre. The difference was significant ($P < 0.05$).

Table 4: Assessment of practice

Questionnaire	Yes	No	P value
Have you ever witnessed an ADR?	60%	40%	0.24
Have you ever reported ADR to monitoring centres?	28%	72%	0.01
Have you ever been trained on how to report an ADR?	54%	46%	0.12
Have you ever filled an ADR form?	15%	85%	0.02

Table IV shows that 60% had witnessed an ADR, 54% had received training on how to report ADR's, 28% had actually reported ADRs to monitoring centre, 75% had seen ADR form but only 15% had filled an ADR form ever. The difference was significant ($P < 0.05$).

Discussion

The history of ADR monitoring dates back to about one seventy years ago since the thalidomide disaster that caused phocomelia in thousands of children in many countries. Pharmacovigilance is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems [5].

Numerous studies revealed that ADR underreporting is linked to the gaps among

health care professionals (HCPs) [6]. All HCPs in the country need to report any suspected adverse drug reaction in order to facilitate immediate and appropriate actions to be taken to prevent or minimize medicine-related injuries for other patients in the future [7,8]. The present study was conducted to assess knowledge, attitude and practice of pharmacovigilance among healthcare professionals.

We found that among doctors, there were 21 males and 36 females, among pharmacists, 18 were males and 20 females and among nursing staff, there were 14 males and 28 females. We found that 70% correctly defined pharmacovigilance, 81% replied correct regarding role of pharmacovigilance, 74% correctly answered regarding which healthcare professionals are responsible for ADR reporting, only 30% knew how to and where to

report ADR's and 25% knew how to fill an ADR form. 78% had correct idea regarding pharmacovigilance programme of India and 48% replied correctly regarding which body is responsible for monitoring in India.

Gupta *et al* [9] in their study on 150 participants, pretested questionnaires were distributed among the healthcare professionals and 101 responded. 62.4% healthcare workers gave correct response regarding the definition of pharmacovigilance. 75.2% of healthcare workers were aware regarding the existence of a National Pharmacovigilance Program of India. 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 centre. 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.

Kassa *et al* [10] in their study used a structured self-administered questionnaire that was used to collect data on KAP among selected health care providers by the convenience sampling method. Out of 120 questionnaires distributed, 114 respondents filled and returned, giving a 95% response rate. From total, 49 (43%) were nurses, 26 (22.8%) physicians, 17 (14.9%) pharmacy professionals, 12 (10.5%) health officers, and 10 (8.8%) midwives. About 86 (75.44%) study participants had an inadequate knowledge towards ADR reporting, and half of participants failed to report the adverse drug reactions they encountered. But the majority of participants (84, 73.68%) had a favorable attitude towards ADR reporting. Nurses, health officers and physicians were found to be less likely to have adequate knowledge on ADR reporting compared to pharmacy professionals.

We found that 82% replied that pharmacovigilance programme should be taught in detail, 92% consider ADR reporting as a professional obligation, 93% believe ADR form is complex to fill and 73% consider opening of maximum number of ADR monitoring centres. We observed that 60% had witnessed an ADR, 54% had been trained regarding how to report ADR, 28% had reported ADRs to monitoring centre, and only 15% had actually filled an ADR form. Vohra *et al* [11] included 215 health care personnel working in a medical college. The mean KAP scores of physicians were found to be 5.75, 4.44 and 1.75 respectively. The KAP score of postgraduate students was 5.5, 4.25 and 1.5 respectively. The KAP score of final year MBBS students was 5, 3.4, and 1.4 respectively, and that of interns was 4, 4.2 and 1.4 respectively. The KAP score of pharmacists was 3.5, 2 and 1 respectively, and that of nurses was 2.75, 2.25 and 0.8 respectively. It was found that mean score of physicians and postgraduate students was higher than interns and final year MBBS and much higher than nurses and pharmacists.

Conclusion

Authors found that though healthcare professionals are very positive regarding need of ADR monitoring and also have fair degree of knowledge regarding pharmacovigilance but they lag in terms of knowledge regarding the reporting process, filling of ADR form. Also practice of ADR reporting is found to be deficient among them, they find filling of ADR reporting form a little bit complex thus necessitating the conduct of regular training sessions for health care professionals wherein they should be trained in depth about filling of ADR forms, the process of reporting, where to report, how to report etc. so that Pharmacovigilance program gets a further boost.

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