

Knowledge, Attitude & Practice of Pharmacovigilance among Health Care Professionals & Medical Students in North IndiaRajit Sahai¹, Sanjay Kumar Verma², Neha Srivastava Sahai³¹Assistant Professor, Department of Pharmacology, Naraina Medical College & Research Centre, Kanpur, U.P.²Associate Professor, Department of Pharmacology, Muzaffarnagar Medical College and Hospital, Muzaffarnagar, U.P.³Reader, Department of Prosthodontics, Rama Dental College, Hospital & Research Centre, Kanpur, U.P.

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Abstract:

Background: Adverse drug reaction (ADR) according to WHO is defined as a response to a medicine which is noxious, unintended & which occurs at doses normally used in man for diagnosis, treatment, prevention of disease or modification of physiological functions. As per WHO, Pharmacovigilance is defined as science & activities related to detection, assessment, understanding & prevention of adverse drug effects or any drug related problems. It aims at enhancement of patient safety by assessing risk-benefit profile of the medicines. Hence this study was conducted to assess the knowledge, attitude & practice towards pharmacovigilance among the students, doctors, nurses & pharmacists.

Materials and Methods: This cross sectional study was conducted amongst doctors, nurses, pharmacists, helping staff & undergraduate medical students from Naraina Medical College & Research Centre and Rama Dental College, Hospital & Research Centre. A questionnaire was handed out to each and every participant and the response was recorded. The study was conducted for 3 months (April 2023 to June 2023). The questionnaire consisted of three sections which included questions on knowledge & awareness, attitude & practice. Each question consisted to multiple options out of which the participants had to choose single most appropriate option.

Results: A total of 500 health professionals participated in the study out of which 244 were medical students (MBBS and BDS), 152 were doctors and 104 were other health care professionals. Students who belonged to mostly second professional of MBBS & BDS fared better in the knowledge aspect of questionnaire. Practicing doctors and physicians (50% average of correct responses in knowledge) of the college though were aware of pharmacovigilance. Other health care practitioners (39.4%) which included nursing staff and various technicians were not so verse with pharmacovigilance. Practicing physicians (71%), students (100%), and other healthcare professionals (58%) had a positive attitude towards reporting of ADRs but what came as the biggest hindrance is the thought of legal repercussions of reporting ADRs.

Conclusion: There is a need for the introduction of pharmacovigilance in all curriculums of medicine both at graduate and undergraduate level. So that we can model a vigilant society which could be helpful in both recognizing as well as reporting ADR for the better good of the society.

Keywords: Adverse Drug Reactions; Pharmacovigilance; Knowledge; Attitude; Practice.

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Introduction

Adverse drug reaction (ADR) according to WHO is defined as a response to a medicine which is noxious, unintended & which occurs at doses normally used in man for diagnosis, treatment, prevention of disease or modification of physiological functions [1]. ADRs have been reported as one of the leading causes of morbidity, prolonged hospitalization, mortality, ultimately leading to increased health care costs [2, 3]. As per a study which was conducted in England between the years 1999-2008 ADR's were related to 0.9%

of all emergency hospital admissions & 26,399 deaths [4]. Also, two meta-analysis of observational studies show a proportion of ADR related hospital admissions ranging between 28.9% - 52.0% [5]. Therefore reporting of an ADR is necessary & is an efficient way to improve safety of drugs & patients [6].

As per WHO, Pharmacovigilance is defined as science & activities related to detection, assessment, understanding & prevention of adverse

drug effects or any drug related problems [7]. It aims at enhancement of patient safety by assessing risk-benefit profile of the medicines [8]. The Pharmacovigilance programme of India was started in the year 2010 with the aim of monitoring of ADRs in the country. The bigger goal however is to uphold public health by assuring safety of medicinal products. The key professionals in prescribing, dispensing, administering, storage & disposal of medicines include doctors, nurses & pharmacists therefore pharmacovigilance requires their attention. Hence ADR reporting by them will most likely increase patient safety [9]. Studies suggest that ADR reporting via health care providers is linked to their knowledge, attitude & practice about pharmacovigilance [10].

Additionally, undergraduate medical students will be the future doctors of our society hence knowing about their knowledge, attitude & practice will be in guide their teaching of pharmacovigilance. Hence this study was conducted to assess the knowledge, attitude & practice towards pharmacovigilance among the students, doctors, nurses & pharmacists.

Material & Methods

This cross sectional study was conducted after getting ethical clearance from the Institutional

ethics committee (RDCHRC/ETHICSCOMMITTEE/A/ 11/9/4/22). It was conducted amongst doctors, nurses, pharmacists, helping staff & undergraduate medical students from Naraina Medical College & Research Centre and Rama Dental College, Hospital & Research Centre. A questionnaire (Appendix-1) was handed out to each and every participant and the response was recorded. The study was conducted for 3 months (April 2023 to June 2023).

The questionnaire consisted of three sections which included questions on knowledge & awareness, attitude & practice. Each question consisted to multiple options out of which the participants had to choose single most appropriate option.

Results

This study was conducted at Naraina Medical College & Research Centre & Rama Dental College, Hospital & Research Centre to assess the knowledge, attitude and practice of pharmacovigilance. A total of 500 health professionals participated in the study out of which 244 were medical students (MBBS and BDS), 152 were doctors and 104 were other health care professionals. They were all handed over a questionnaire according to which they all were assessed.

Scores based on knowledge (**Figure 1**)

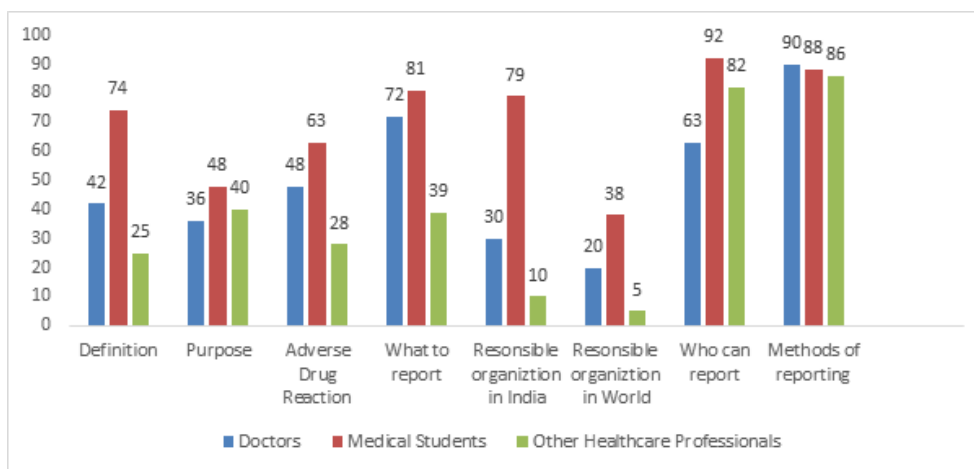


Figure 1: Assessment of knowledge in different groups of health professionals*

*Expressed as percentage of individual category of health professional for correct response

Questions on attitude were asked and responses of the groups of health professionals were recorded for each option and expressed as frequency in **Table 1**.

Table1: Attitude of practicing doctors, students and other health care professionals

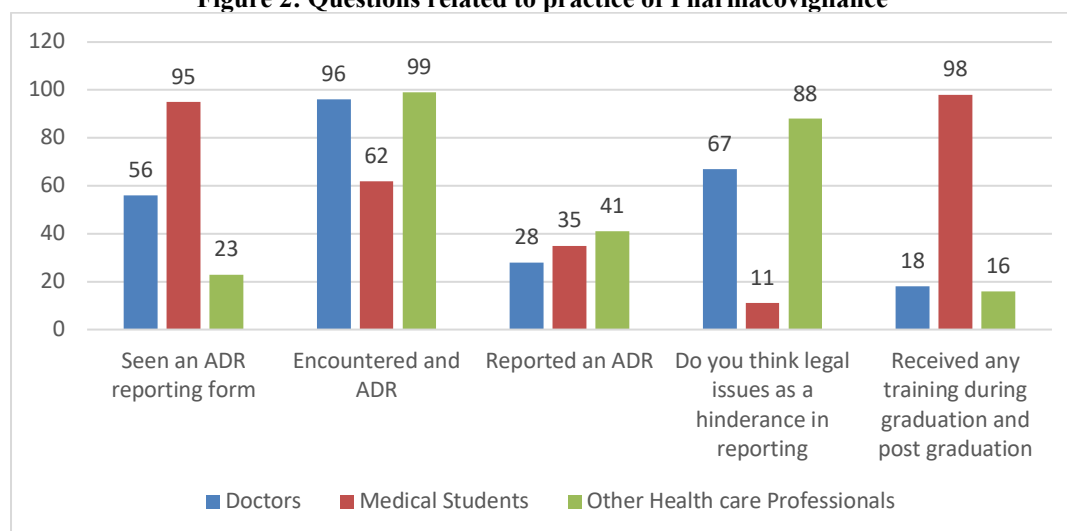
Question	Yes	Can't Say	No
Is reporting ADRs important?			
Doctors	102*	43*	7*
Students	207*	31*	6*
Other Healthcare Professionals	67*	5*	32*
Is it a professional obligation?			
Doctors	62*	79*	11*

Students	231*	7*	6*
Other Healthcare Professionals	28*	44*	32*
Are sensitization programs necessary?			
Doctors	80*	49*	23*
Students	236*	5*	3*
Other Healthcare Professionals	52*	13*	39*
Would you adopt ADR reporting behavior?			
Doctors	109*	33*	10*
Students	244*	0*	0*
Other Healthcare Professionals	72*	31*	21*
Mandatory posting in Pharmacovigilance?			
Doctors	103*	18*	31*
Students	207*	17*	20*
Other Healthcare Professionals	84*	19*	1*
Is educating about pharmacovigilance need of the hour?			
Doctors	67*	50*	35*
Students	240*	4*	0*
Other Healthcare Professionals	93*	7*	4*
Is maintaining confidentiality necessary?			
Doctors	129*	4*	19*
Students	200*	17*	27*
Other Healthcare Professionals	47*	33*	24*

*Expressed as frequency

After the questionnaire on knowledge and attitude questions were put forth about practice of pharmacovigilance. This part of questionnaire was marked as positive response as yes and negative response as no. The graph shows only the positive responses of each group in percentage (Figure 2).

Figure 2: Questions related to practice of Pharmacovigilance*



*Expressed as percentage

Discussion

The present study was conducted to observe knowledge, attitude & practice of Pharmacovigilance among health care professionals and medical students at medical college in North India. This was a questionnaire-based study.

In the present study we found that medical students who belonged to mostly second professional of MBBS & BDS fared better in the knowledge aspect of questionnaire which may be due to the introduction of pharmacovigilance in their teaching curriculum. Practicing doctors and physicians (50% average of correct responses in knowledge) of the college though were aware of pharmacovigilance.

Other health care practitioners (39.4%) which included nursing staff and various technicians were not so verse with pharmacovigilance. This was lower than study conducted by Gupta et. al [11]. and This emphasized that pharmacovigilance should be included in teaching of all streams of medicine.

The findings of second part (attitude) of the questionnaire were in a stark contrast to the knowledge. Though, medical students fared better in similarity to the knowledge section. What came as surprise that practicing physicians (71%), students (100%) and other healthcare professionals (58%) had a positive attitude towards reporting of ADRs but what came as the biggest hindrance is the thought of legal repercussions of reporting ADRs (healthcare professionals 67%, Nursing Professionals 88%) as well as their personal scrutiny similar to Tandon et.al [12]. Though they all agreed that ADR reporting behavior should be promoted by proper sensitization (73%) of all practicing healthcare practitioners beginning mandatory posting (78%) in Department of Pharmacology during internship as well as conducting regular contact sessions it was more than in study conducted by Srinivasan et. Al [13].

Majority of health care professional in this study had seen an ADR form (58%) but had not reported it thinking it to be the usual side effect of the drug (85.67%). Nursing and paramedical professionals though had reported ADRs during their duties (41%).

Conclusion

There is a need for the introduction of pharmacovigilance in all curriculums of medicine both at graduate and undergraduate level. So that we can model a vigilant society which could be helpful in both recognizing as well as reporting ADR for the better good of the society.

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Appendix-1: Questionnaire**Knowledge & Awareness of Pharmacovigilance & ADR's**

1. Which amongst all is most specific way to define Pharmacovigilance:
 - a) It is the science & activities related to detection, assessment, understanding & prevention of adverse drug reactions
 - b) It is an activity used for monitoring of adverse drug reactions in a hospital
 - c) It is science involving knowledge of adverse drug reactions
 - d) It is a process to determine the safety of a drug
 - e) Don't know
2. Which amongst all better explains the purpose of Pharmacovigilance:
 - a) To determine the predisposing factors of an adverse drug reaction
 - b) To analyze the prevalence of adverse drug reactions
 - c) To boost patient safety in relation to drugs
 - d) Don't know
 - e) To enhance doctor patient relationship
3. Which amongst the following is the correct way to define an adverse drug reaction:
 - a) Any experience associated with use of a drug include any side effect, injury, toxicity or sensitivity reaction or significant failure of expected drug action
 - b) Any response to a drug that is noxious & unintended & occurs at doses normally used in man for prophylaxis, diagnosis & therapy of disease or for the modification of the physiological function
 - c) Impairment resulting from use of a substandard/counterfeit drugs
 - d) Any drug causing teratogenicity in a newborn
 - e) Any harm occurring due to use overdose of drugs
4. Amongst all which adverse drug reactions should be reported:
 - a) Adverse drug reaction occurring due to use of a new drug
 - b) Adverse drug reaction occurring due to use of vaccines
 - c) All serious adverse drug reactions
 - d) Adverse drug reactions occurring due to use of older drugs
 - e) All of the above
5. Which is the organization in India responsible for monitoring of adverse drug reactions:
 - a) WHO
 - b) Pharmacy council of India
 - c) Indian Pharmacopoeia Commission
 - d) Ministry of health & family welfare
 - e) National Medical Commission
6. Which of the following is the International monitoring body for adverse drug reaction:
 - a) United Nations
 - b) Uppsala Monitoring Centre
 - c) WHO
 - d) IMF
 - e) NATO
7. According to you who can report an adverse drug reaction:
 - a) Doctor
 - b) Nurse
 - c) Pharmacist
 - d) Patient
 - e) All of above
8. Which is preferred method according to you for reporting of adverse drug reactions:
 - a) Email
 - b) Telephone
 - c) Direct contact
 - d) Post
 - e) Website

Attitude questions to pharmacovigilance & ADR's

1. According to you is reporting of an adverse drug reaction important:
 - a) Yes

- b) Can't Say
- c) No
- 2. Is reporting an adverse drug reaction an professional obligation for you:
 - a) Yes
 - b) No
 - c) Can't Say
- 3. Sensitization programmes to pharmacovigilance is necessary in hospitals:
 - a) Yes
 - b) No
 - c) Can't say
- 4. Would you be interested in reporting an adverse drug reaction:
 - a) Maybe
 - b) Yes
 - c) No
- 5. Pharmacovigilance postings should be made mandatory in internship:
 - a) Yes
 - b) No
 - c) Maybe
- 6. Pharmacovigilance should be taught mandatorily to all health care providers:
 - a) No
 - b) Maybe
 - c) Yes
- 7. Should confidentiality of the patient suffering from ADR be maintained:
 - a) No
 - b) Yes
 - c) Maybe

Practice questions towards Pharmacovigilance & ADR's

- 1. Have you ever seen an ADR reporting form:
 - a) Yes
 - b) No
- 2. Have you ever encountered a patient with an ADR:
 - a) Yes
 - b) No
- 3. Have you ever reported an ADR:
 - a) Yes
 - b) No
- 4. Legal issues concerning ADR reporting is the major reason behind underreporting:
 - a) Yes
 - b) No
- 5. Have you received any training during graduation/post-graduation regarding pharmacovigilance:
 - a) Yes
 - b) No