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A Questionnaire based study to assess Knowledge, Attitude and Practice of Pharmacovigilance among Second year MBBS students in a Tertiary care teaching Hospital .

Dr.T.Meenakshi[1], *Dr.M.Kulandaiammal[2], Dr.Sangavai Mathiazhagan
Department Of Pharmacology, Govt Stanley Medical College, Chennai- 01
Corresponding author[*] Dr.M.Kulandaiammal[2]

I. Introduction

Pharmacovigilance (PV) is the sum of activities related to the detection, assessment, understanding, and prevention of ADRs caused by drugs [1]. In India, the national Pharmacovigilance Program of India (PvPI) was established by the Central Drugs Standard Control Organization (CDSCO) in 2004 to monitor ADRs and to provide drug safety reports to the WHO-ADR monitoring center in Uppsala, Sweden [2]. It is evident that under-reporting of suspected ADRs by health professionals is a widespread problem in India [3] In order to improve the reporting of ADRs, it is important to improve the Knowledge, Attitude and Practice (KAP) of the healthcare professionals regarding ADR reporting and Pharmacovigilance. First exposure to patients happens during second year of MBBS when the students go for OP and ward postings. If we create proper awareness about the ADR reporting procedures during that period, it will be useful for improving the reporting rate and also they become completely aware of the importance of ADR reporting when they turn out to be practitioners. Therefore this study was planned to evaluate the knowledge, attitude and practices (KAP) towards Pharmacovigilance in second year MBBS students and improve the KAP by designing awareness programs and practical classes

II. Objective

To assess knowledge, attitude and practice of Pharmacovigilance among second year MBBS students in a tertiary care teaching hospital

III. Materials And Methods

Study Design - Cross sectional Questionnaire based study
Study Centre – Department of pharmacology, Government Stanley Medical college
Study Population – II year MBBS students
Sample size- 250 students

Inclusion criteria:
1. Second MBBS students both girls and boys
2. Students willing to give written informed consent

Exclusion criteria
1. Students not willing to give informed consent

The study was conducted after getting approval from Institutional ethics committee.

II year MBBS students who were willing to participate in the study were explained about the purpose of the study and informed consent was obtained. A questionnaire containing 30 questions (10 to test knowledge, 10 to test Attitude and 10 to test practice) were given to each student .Any doubts regarding questionnaire were clarified by the investigator.
30 minutes were given for filling the questionnaire.
The results were analyzed statistically

IV. Results

250 questionnaires were distributed among the students and 236 students responded. The response rate was 94 %

Knowledge

51 % students gave correct response regarding definition of ADR. 84% students think ADR and Adverse drug reactions are different.72 % answered that all health care professionals can report ADR. 47% students think that ADR reporting is mandatory.68% students gave correct response regarding the definition of pharmacovigilance.19 % answered that WHO causality assessment scale is commonly used for causality assessment.87 % students gave correct expansion for PvPI . 67% correctly expanded (CDSCO). 71% correctly answered the location of National Pharmacovigilance Centre. 61% responded that Uppasala monitoring centre is located in Sweden

Table 1: knowledge related questions and percentage of responses

S.No	Questions	Percentage of students who gave Correct Response	Percentage of students who gave Incorrect Response
1	Define ADR	51%	49%
2	Are Adverse Drug Event and ADR the Same?	84%	16%
3	Who Can Report ADR?	72%	28%
4	Is ADR Reporting Mandatory?	47%	53%
5	What Is Pharmacovigilance?	68%	32%
6	Which method is commonly used for Causality Assessment of ADR?	19%	81%
7	What does PvPI stand for?	87%	13%
8	Where is National Pharmacovigilance Centre in India located?	71%	29%
9	Expand the acronym CDSCO	67%	33%
10	Where is UMC located?	61%	39%

Attitude

A total of 97% students agreed that reporting of ADR is necessary. 81 % think that ADR reporting benefits both patients and doctors. 68% were of the view that pharmacovigilance should be included in pharmacology practical classes. 61 % think ADR reporting is a part of professional obligation of Doctors. 63% feel that medical students play an important role in ADR reporting.52 %think discussion on ADR during clinical posting is relevant. 32 % think collecting box at all clinical departments is helpful for proper reporting.71 % students think that drug history is an important part in history taking. 63%think treatment of ADRs increase the financial burden of the patients and health system.81% think that ADRs can be prevented by proper knowledge about the drug interactions.

Table 2: Attitude related questions and percentage of responses

S. No	QUESTIONS	Percentage of students who gave Positive response	Percentage of students who gave Negative response
1	Do you think ADR reporting is necessary?	97%	3%
2	Do you think ADR reporting benefits both patients and doctors?	81%	19%
3	Should ADR reporting be included under Pharmacology practical?	68%	32%
4	Do you think ADR reporting is a part of professional obligation of all related to health care?	61%	39%
5	Do you think medical students could play a role in ADR reporting?	63%	37%
6	Do you think discussion on ADR during clinical posting has any relevance?	52%	48%
7	Do you think collecting box at all clinical departments is helpful for proper reporting?	32%	68%
8	Do you think that drug history is an important part in history taking?	71%	29%

9	Do you think treatment of ADRs increase the financial burden of the patients and health system?	63%	37%
10	Do you think that ADRs can be prevented by proper knowledge about the drug interactions?	81%	19%

Practice

57% have seen the ADR reporting form. 42% have seen ADRs in their ward postings. Merely 2 % have played role in ADR reporting and 1 % had visited ADR Monitoring Centre. None has done causality assessment of ADRs.12 % have been trained in ADR reporting.1% have seen de challenging and re challenging done in cases of ADRs.91% students have taken Drug history in patients when taking history during ward postings.11 % have seen an ADR being treated. 3% students have seen patients with serious Adverse drug reaction being admitted in ICU.

Table 3: Practice-related questions and percentage of responses

S.NO	QUESTIONS	Percentage of students who gave positive response	Percentage of students who gave Negative response
1	Have you seen an adverse drug reporting form by CDSCO?	57%	43%
2	Have you ever seen a case of ADR during your ward posting?	42%	58%
3	Have you ever visited any ADR monitoring center?	1%	99%
4	Have you ever played any role in reporting ADR from your institution?	2%	98%
5	Have you done causality assessment of ADRs?	0%	100%
6	Have you been trained in ADR reporting?	12%	88%
7	Have you seen de challenging and re challenging being done in cases of ADRs?	1%	99%
8	Have you taken drug history in patients when taking history during ward postings?	91%	9%
9	Have you seen an ADR being treated?	11%	89%
10	Have you seen any patient with serious Adverse drug reaction being admitted in ICU ?	3%	97%

V. Discussion

Spontaneous reporting of ADR is vital for the success of pharmacovigilance program. There are many studies to evaluate the KAP of health care providers toward pharmacovigilance program, but only few studies have been done among undergraduate MBBS students [4,5,6,7] This study is one of the few studies done among second year MBBS students regarding KAP of pharmacovigilance. From this study, it is clear that students have adequate knowledge and good attitude towards pharmacovigilance. The aim of pharmacovigilance is to ensure patient safety and rational use of medicines. Major reason for under reporting is lack of skill in pharmacovigilance , which was reflected in our study, and it corroborates with the finding of studies done previously.[9,10] It can be overcome by educational intervention programs like incorporation of it in undergraduate practicals, continuous medical education (CME), and workshops on pharmacovigilance.[11]

VI. Conclusion

Students showed better Knowledge and attitude, but limited practice toward pharmacovigilance. The findings of the study suggest a huge scope for improving the awareness about pharmacovigilance among the students who will be the backbone of health care delivery in future. For this, there is a need for involvement of Undergraduate students in ADR reporting and training them in filling the CDSCO forms and causality assessment.

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