

# The magnitude of sensitization of pharmacovigilance among undergraduate medical students in a tertiary care teaching hospital – A questionnaire based study

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**Abstract:** *Background:* Pharmacovigilance (PV) is an evolving branch of medical education. It helps in identifying the negative effects of drugs and safeguards the public and patients from them. Adverse Drug Reaction (ADR) reporting will have an important role in enhancing the safer and smarter use of drugs among the population. *Objectives:* To study the magnitude of sensitization of pharmacovigilance among undergraduate medical students. To study the Knowledge, Attitude, and Practice about Pharmacovigilance among the undergraduate students. *Methods:* Knowledge, Attitude, and Practice about Pharmacovigilance and ADR reporting were assessed among the undergraduate (UG) students before and after sensitization. *Results:* The study showed that undergraduate medical students have insufficient knowledge and awareness about Pharmacovigilance and ADR reporting. The sensitization program helped to enhance the knowledge and awareness about PV & ADR reporting among UG students. *Conclusion:* The inclusion of sensitization programs regarding drug safety during the undergraduate level along with their routine curriculum can help to strengthen the Pharmacovigilance Program of India (PvPI).

**Keywords:** Pharmacovigilance, Questionnaire, Sensitization program, Undergraduate

## Introduction

Pharmacovigilance is the "Science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems"[1]. Pharmacovigilance has constantly grown in importance during the last 15 years, considering the number of adverse drug reactions (ADR's) reported to the fact that several hospital admissions are due to ADR's [2]. Despite the fundamental importance of reporting suspected adverse drug reactions, less than 10 percent of serious adverse drug reactions are reported [3].

Pharmacovigilance is needed in every country because data derived from within the country or region may have greater relevance and educational value and may encourage national regulatory decision-making [4]. Objectives of pharmacovigilance can be met with the voluntary reporting of adverse drug reactions (ADRs) by

healthcare professional which is an integral component of patient care [5].

Voluntary reporting can identify unusual and unexpected events which are not revealed by clinical trials [6]. Underreporting of the ADRs is a challenge for the pharmacovigilance program. Therefore, this study aimed to evaluate the magnitude of sensitization about knowledge, attitude, and perceptions about pharmacovigilance among undergraduate medical students in a tertiary care hospital.

### Objectives:

1. To study the magnitude of sensitization of pharmacovigilance among undergraduate medical students.
2. To study the Knowledge, Attitude, and Practice about Pharmacovigilance among the undergraduate students.

**Material and Methods**

The study included the second phase MBBS students from Gadag Institute of Medical Sciences (GIMS), Gadag who were willing to participate in the pharmacovigilance sensitization program were enrolled in this study. It is an online questionnaire-based study. A purposive sampling method was used. The participants who were not willing to participate and did not attend the sensitization program were excluded. A predesigned questionnaire consisting of 15 multiple-choice questions (MCQs) was used to collect the data. Institutional Ethics Committee (IEC) approval was obtained before the commencement of the study (IEC approval-GIMS/IEC/3/2018-19).

*Method of collection of data:* Second-year Undergraduate students of GIMS, Gadag participated in the sensitization program by filling out the online form containing a predesigned questionnaire. The students were explained regarding their role in the study and the importance of the program before the commencement of the study. Before and after the sensitization program students were instructed to fill out the Google forms and submit them online.

*Analysis of data:* The questionnaires were analyzed in the Microsoft Excel worksheet. Results were tabulated and expressed in the form of percentages and graphs.

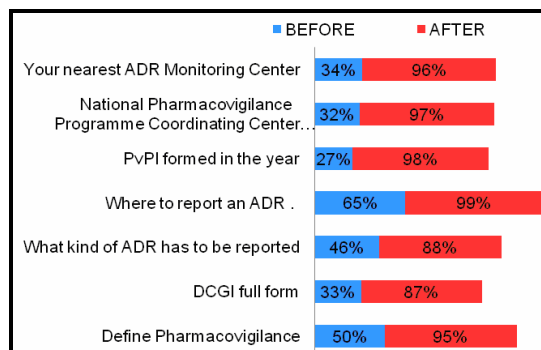
**Results**

The questionnaire was distributed among 120 students. 109 were interested and responded to all the questions. The response rate is 90.83%. Data is tabulated in the form of a percentage of responses given by participants.

Graph 1 shows an assessment of knowledge among the participants. The definition of PV was known to 50% of students before the sensitization program but post-sensitization 95% of students answered appropriately. The knowledge regarding the nearest ADR monitoring center and the location of the national PvPI center was seen in 34% and 32% of students respectively which improved to 96% and 97% respectively. PvPI was formed in 2010 and was known to 27% of students before sensitization, here the knowledge regarding this increased to 98% post-

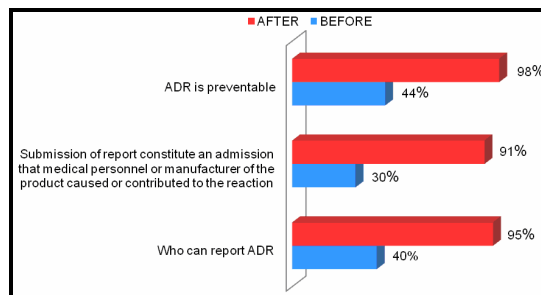
sensitization. Any suspected ADR should be reported and DCGI full form as Drug Controller General of India were answered by 88% and 87% post sensitization respectively. Overall the knowledge regarding the PVPI and ADR reporting increased to 50-70% after the sensitization program.

**Graph-1:** Assessment of knowledge



Graph 2 gives the attitude of the participants regarding ADR reporting. Only 44% answered ADR is preventable pre-sensitization but post-sensitization 98% answered correctly. 91% told no need to report the medical personnel or manufacturer names in the ADR form when compared to 30 % presensitization. Anyone can report the ADR told by 95% of students as compared to 40% in pre-sensitization. 55-60% of perceived the knowledge about ADR preventability, who can report the ADRs and submission of the report does not constitute an admission of contribution to reaction.

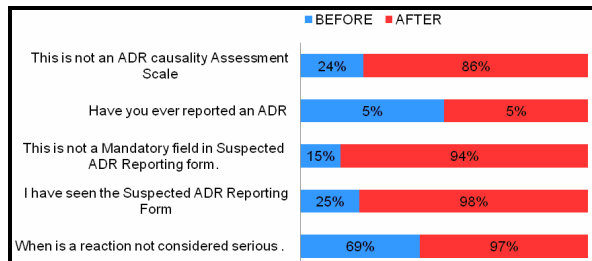
**Graph-2:** Assessment of attitude



Graph 3 shows the assessment of practice. Post sensitization, 98% of participants answered that they had seen ADR forms, and 86% identified correctly the types of ADR causality assessment scales. Only 5% of participants have reported ADR so far. Post-sensitization 94% of participants also got to

know about the mandatory fields in the ADR form and 97% of participants answered regarding when the reaction is considered serious. Perception of ADR-related practice increased significantly about the mandatory field in ADR form (79%) and causality assessment scale (62%) post sensitization.

**Graph-3:** Assessment of practice



**Discussion**

PV is an arm of patient care. So, spontaneous ADR reporting plays an important role in drug safety. In the study, most of the participants were unaware of the correct meaning of PV, the role of PVPI, the location of the PV center, the most commonly used scales to establish the causality of an ADR, who can report the ADRs, and what type of ADRs to report. This study shows that there is a lack of knowledge regarding PV and ADR reporting systems. This may be due to limited awareness about PV.

The knowledge of PV assessed through this study is similar to the various previous studies reported in the literature [7-9]. The various studies mention that conducting training and CME for all health care professionals like students, doctors, nursing staff, pharmacists, and paramedical staff. So they can also get awareness about ADR & reporting of ADR [10-11].

Educating patients about filling ADR forms can lead to the future improvement of pharmacovigilance processes and have a greater influence that patients may exert on the safety monitoring of medicines, which, in turn, can enhance the effectiveness of the pharmacovigilance system [12].

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Unfamiliarity with pharmacovigilance, a low level of ADR-reporting skills, a lack of knowledge combined with negative attitudes like ignorance, fear of legal liability, and lack of importance is thought to be related to the current inadequate response to many ADRs [13-16].

The majority of educational interventions consisted of lectures, occasionally combined with small, interactive working groups. Real-life learning initiatives have shown that healthcare students are capable of contributing to patient care while increasing their ADR-reporting skills and knowledge [17].

The undergraduate students who are not taught about the PV will have less knowledge. Now the NMC curriculum has added the ADR reporting which creates awareness among the students. The sensitization programs like the present study will further enhance awareness and can lead to faster and more accurate ADR reporting. Knowledge of PV can further be increased by conducting hands-on training, ADR reporting workshops, quizzes, and rewarding the students for reporting. Regular visits to the PV center to observe the performance will help in understanding the need for drug safety among the people.

**Conclusion**

Our study showed that there is insufficient knowledge and awareness about PvPI in the participants. This study shows that the sensitization program has increased the knowledge, attitude, and practice of students by 50-70%. Conducting training programs, workshops, and interactive lectures for medical students during their routine curriculum might help to strengthen PvPI and ADR reporting. Real-life pharmacovigilance training increases their knowledge and awareness which can also assist healthcare professionals. The results of the present study suggest that an educational intervention in the form of CME/workshop/lectures/real-life pharmacovigilance training can increase awareness of PV.

**Conflicts of interest:** There are no conflicts of interest.

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