

#### Research

# KNOWLEDGE, ATTITUDE AND PRACTICE ABOUT PHARMACOVIGILANCE AMONG THE MEDICAL INTERNS IN A TERTIARY HEALTHCARE CENTRE IN KULASEKHARAM

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#### Abstract

Background: Drug therapy is an integral part of medical management. It has many beneficial effects, but some major disadvantages are side effects and adverse drug reactions (ADRs). Hence this study aims to assess the attitude and application of Pharmacovigilance among Interns. Materials and Methods: A Cross-Sectional, Questionnaire-based study was conducted at Sree Mookambika Medical College (SMIMS), Kulasekharam, Tamil Nadu. 85 Interns of SMIMS and Interns who are willing to participate in the study. The questionnaire was used to assess the awareness (perception of a situation or a fact), knowledge (theoretical or practical understanding of a subject) and the method of application of pharmacovigilance among the interns. Result: A questionnaire showed that about 31% of interns only had knowledge, 69.60% had a satisfactory response to attitude, and 75% had a satisfactory response regarding the Practice of Pharmacovigilance. In addition, it was noted that most students (68.83%) were not knowledgeable about pharmacovigilance. Still, most students (75%) knew how to report an ADR (adverse drug reaction). **Conclusion:** We can conclude that the overall attitude and practice are better among the interns. However, the knowledge of pharmacovigilance has to improve. It can be done by including pharmacovigilance CME and orientation programs throughout the entire medical curriculum and incorporating better, more efficient and more interesting methods to teach, sensitize, and practice pharmacovigilance.

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# INTRODUCTION

Drug therapy is an integral part of medical management. It has many beneficial effects, but some major disadvantages are side effects and adverse drug reactions (ADRs). ADR is defined by World Health Organization (WHO) as "a response to a drug that is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or the modification of physiological function".

ADR is responsible for significant morbidity and mortality, which has been proven to be the fourth to the sixth leading cause of death. [1] Pharmacovigilance is "The science and activities related to the detection, assessment, understanding and prevention of adverse effects or other drugrelated problems. [2] The awareness of ADRs can decrease the irrational use of an inappropriate pharmacy. [3]

An Expert in anything was once a Beginner'. Interns today are the future faces of tomorrow's medicine. So, it is mandatory that, as doctors, they should not only be trained to diagnose diseases and manage the condition appropriately, but they should also have proficient knowledge of the various reactions of the drugs they are going to prescribe. Moreover, they should also be taught to report a response as soon as it comes to his notice. Hence this study aims to assess the attitude and application of Pharmacovigilance among Interns.

## **MATERIALS AND METHODS**

A Cross-Sectional, Questionnaire-based study was conducted at Sree Mookambika Medical College (SMIMS), Kulasekharam, Tamil Nadu.

## **Inclusion Criteria**

85 Interns of SMIMS and Interns who are willing to participate in the study.

#### **Exclusion Criteria**

Interns unwilling to give informed consent, First, second, third and final year MBBS. Data Collection was obtained using a Questionnaire to be filled out by the subjects.

A questionnaire was designed according to the precedence set by similar studies. This questionnaire was used to assess the awareness (perception of a situation or a fact), knowledge (theoretical or practical understanding of a subject) and the method of application of pharmacovigilance among the interns. The questionnaire consisted of 15 questions (6 to test knowledge, 5 to test attitude and 4 to test Practice about Pharmacovigilance among Interns).

The questionnaire was administered to 85 interns (from all specialities) posted at SMIMS, Kulasekharam. Informed consent was obtained, and the participants were briefed regarding the questionnaire. However, participants were requested not to consult anyone regarding filling out the questionnaire, and anonymity was maintained regarding their names.

The questionnaire had 15 questions, except question number 6 (they had to write their answer). All other questions had answers given in options, which the interns had to choose regarding their perspectives.

The questionnaire was then evaluated. One point was given to each question, a maximum of 15 points. It was then analyzed by grading the responders into two categories: Unsatisfactory and Satisfactory. The range was categorized as: for knowledge: Unsatisfactory (1-2), Satisfactory (3-6). For Attitude: Unsatisfactory (1-2), Satisfactory (3-5). For practice: Unsatisfactory (1-2), Satisfactory (3-4). Data were analyzed using the Chi-square test and T-test, and correlation technique.

# **RESULTS**

The questionnaire was administered to 85 participants. The mean scores were evaluated from the total scores of each participant. It was noted that the mean score of practice was highest compared to the mean scores of knowledge and attitude, of which the knowledge mean score was the lowest.

Knowledge of Pharmacovigilance among the participants, 75% understood pharmacovigilance. 24% knew the serious adverse events. 45% knew who could report ADR. 21% knew whom ADR had to be reported. 12% knew within particular days, ADR should be reported. 10% knew the drugs had been withdrawn from the market due to ADR reporting [Table 1].

Regarding the attitude of pharmacovigilance among the participants, 56% knew ADR reporting is mandatory in hospitals. 78% knew CRRI had the suspicion of an ADR during the prescription of the drug. 38% knew interns should report the ADR voluntarily to the senior doctor. 82% knew ADR reporting from a tertiary health centre was required. 94% knew the hospital's financial rewards ADR reporting by an intern [Table 2].

In pharmacovigilance practice, 92% knew how often to report an ADR to the ADR monitoring centre (AMC). 89% knew what to do when they came across an ADR. 21% knew How frequently include ADR as a differential diagnosis in any disease. 98% knew the factors to discourage an intern from ADR reporting [Table 3].

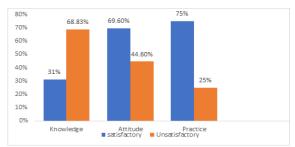


Figure 1: Satisfactory and unsatisfactory responses to Questions based on Pharmacovigilance among Interns

A questionnaire showed that about 31% of interns only had knowledge, 69.60% had a satisfactory response to attitude, and 75% had a satisfactory response regarding the Practice of Pharmacovigilance. In addition, it was noted that most students (68.83%) were not knowledgeable about pharmacovigilance. Still, most students (75%) knew how to report an ADR (adverse drug reaction).

Table 1: Knowledge of Pharmacovigilance

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Satisfactory responses (%)	
What do you understand by pharmacovigilance?	75%
What constitutes serious adverse events?	24%
Who can report ADR?	45%
To whom does ADR have to be reported?	21%
ADR reported it should be sent within how many days of suspected ADR?	12%
Mention any familiar drugs withdrawn from the market due to ADR reporting.	10%

Table 2: Attitude of Pharmacovigilance

Satisfactory response (%)	
Should ADR reporting be mandatory in hospitals?	56%
Should the CRRI have the suspicion of an ADR during the prescription of the drug?	78%
Should the interns report the ADR voluntarily to the senior doctor?	38%
Is ADR reporting from a tertiary health centre required?	82%
Should ADR reporting by an intern be financially rewarded by the hospital?	94%

Table 3: Practice of Pharmacovigilance

Satisfactory response (%)	
How often do you report an ADR to the ADR monitoring centre (AMC)?	92%
What will you do when you come across an ADR?	89%
How frequently do you include ADR as a differential diagnosis in any disease?	21%
What factors do you think to discourage an intern from ADR reporting	98%

# **DISCUSSION**

Pharmacovigilance is an essential part of the healthcare system nowadays. Gupta SK et al. concluded that pharmacovigilance aims at the early detection of adverse reactions and interactions, the frequency of adverse reactions monitoring, risk factors identification for the adverse reactions and dissemination of the information required to improve the prescription of drugs. [4]

This study was one of the few studies done to assess the medical interns regarding their knowledge, attitude and practice of pharmacovigilance in SMIMS, Kulasekharam.

In a study by Gupta P et al., only 43% are aware of ADR reporting. In contrast, in this study, it was comparatively less than 35 % which shows that in the MBBS curriculum, knowledge regarding ADR has to be given importance. [5]

Despite having unsatisfactory responses towards knowledge of pharmacovigilance, the attitude and practice of ADR reporting are high among medical interns at more than 60% and 70%, respectively. This was because the department of pharmacology laid more emphasis on making them understand the importance of pharmacovigilance by having extra practical demonstrations, case studies, and group tasks related to adverse drug reactions. This was noted in a similar study by Marko et al., which showed that ADR reporting accounted for 90% of medical students despite having reasonably good knowledge of pharmacovigilance. [6]

Patient safety and rational use of medicines is the main aim of pharmacovigilance, which has played a significant role in detecting ADRs. [7]

In a study by Kulmi et al., more than 40% of MBBS students think that ADR reporting is compulsory. Similarly, in this study, 56% of students believe that ADR reporting is necessary, while a study done by Gupta and Udupa identified 89.5% of participants, suggesting the necessity of ADR reporting. [8,9]

According to another study by Ponmary et al., medical interns have adequate knowledge and attitude regarding pharmacovigilance. Similarly, in this study, knowledge and attitude were 31% and 69.6%, respectively. [10]

# Limitation of the study

Only 85 medical interns were included in this study. Including 2nd year, pre-final and final-year MBBS students would have given a better insight into the current state of affairs regarding pharmacovigilance among medical students. This would have helped

acknowledge appropriate measures to improve the knowledge and attitude regarding ADR reporting.

## **CONCLUSION**

This study showed that most students knew how to report an ADR and understood the need for reporting, despite having a low knowledge of pharmacovigilance. Here, the majority respondents agreed that reporting ADR is necessary. So finally, from the study, we can conclude that the overall attitude and practice are better among the interns. However. the knowledge pharmacovigilance has to improve. It can be done pharmacovigilance including **CME** orientation programs throughout the entire medical curriculum and incorporating better, more efficient and more interesting methods to teach, sensitize, and practice pharmacovigilance.

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