



## STUDY ON KNOWLEDGE, ATTITUDE AND AWARENESS OF PHARMACOVIGILANCE AMONG MEDICAL STUDENTS AT A TERTIARY CARE HOSPITAL.

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### ABSTRACT

Pharmacovigilance awareness is essential among medical students to prevent adverse reaction related hospitalization. Hence the aim of this study is to assess the knowledge, attitude and awareness of pharmacovigilance among medical students at a tertiary care hospital.

This questionnaire based study was conducted simultaneously for second, third and fourth year MBBS students and CRRIs. Consenting participants anonymously completed the questionnaire in the classroom in 45 minutes. The questionnaires were collected and analyzed using chi square test and descriptive statistics. The average knowledge of Pharmacovigilance was 65.49% and average awareness was 71.76%. CRRIs and IV years had better knowledge, awareness and more positive attitude of ADR reporting and pharmacovigilance compared to the II years and III years probably due to clinical exposure to ADRs. This study demonstrated that knowledge and attitude towards pharmacovigilance is adequate among healthcare professionals and practice of ADR reporting is catching up

**KEYWORDS :** Awareness, Attitude, Knowledge, pharmacovigilance

### INTRODUCTION:

The World Health Organization (WHO) defines an Adverse drug reaction (ADR) as a response to a drug which is noxious, unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.<sup>1</sup> Pharmacovigilance is defined as "the science and activity related to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems".<sup>2</sup> Though pharmacovigilance programme was started in India in 1982, the awareness about it is much lower.<sup>3</sup> The primary source of information for pharmacovigilance is from spontaneous reporting by health care professionals. Under-reporting of ADRs is a major problem, affecting pharmacovigilance programme of India. Because of under reporting, Indian drug regulators are very much dependent on data and advice from other countries.<sup>4</sup> It has been reported that 2.4-6.5% of the total admissions in the hospitals are due to the adverse reactions, many of which are preventable.<sup>5</sup> Hence the present study was undertaken to study the knowledge, attitude and awareness of pharmacovigilance among medical students at a tertiary care hospital.

**Subjects and Methods:** Study was conducted simultaneously for second, third and fourth year MBBS students and (CRRIs) Compulsory Rotatory Residential Intern after obtaining clearance from Institutional Ethics Committee. A briefing was given about the objective of the study, and the procedure of completing the questionnaire. Informed written consent was taken from each student participating in this study. Consenting participants anonymously completed the questionnaire in the classroom. Total 45 minutes was given to the students to complete the questionnaire. The completed questionnaires of second, third and fourth year MBBS students and CRRIs were collected and analyzed separately and incomplete ones were excluded.

### Materials & methods:

**Design of study:** A cross-sectional comparative study

**Period of study:** December 2015 to February 2016 (3 months)

**Study centre:** Department of Pharmacology, Chengalpattu Medical College

**Study population:** Second, third and fourth year MBBS students and CRRIs

**Sample size:** 300 students

**Selection criteria**

**Inclusion criteria:** Second, third and fourth year MBBS students and CRRIs

### Exclusion criteria:

1. Students who are not willing
2. Incomplete questionnaires

A questionnaire containing twenty-two questions which included 10 Knowledge questions, 6 Attitude questions, and 6 Awareness questions were used. The following parameters were considered in our statistical analysis of pharmacovigilance amongst the medical students of various batches of Govt. Medical College:

1. Question wise knowledge
2. Question wise Awareness
3. Year wise knowledge & Awareness
4. Association between Year of Study and Attitude.

Data was analysed using descriptive statistics with SPSS software version 16.

### RESULTS:

Out of 300 students, 285 students consented for the study and undertook the questionnaire. Out of them 255 completed the questionnaire.

**Table-1. QUESTIONWISE KNOWLEDGE**

SL NO.	QUESTIONS	Students – correct response	% knowledge
1	Define Pharmacovigilance?	234	91.76
2	The important purpose of Pharmacovigilance is	159	62.35
3	Which of the following methods is commonly employed by the pharmaceutical companies to monitor adverse drug reactions of new drugs once they are launched?	227	89.02
4	A serious adverse Event in India should be reported to the Regulatory body within	122	47.84
5	The international centre for adverse drug reaction monitoring is located in	154	60.39
6	One of the following is the agency in Unites States of America involved in drug safety issues	174	68.23

7	Match the ADR reporting systems to the respective countries	114	44.71
8	One among these is a national Pharmacovigilance centre?	172	67.45
9	Which one of the following is the 'WHO online database' for reporting ADRs?	120	47.06
10	The healthcare professionals responsible for reporting ADR in a hospital is/are	194	76.08
<b>Average</b>		<b>167</b>	<b>65.49</b>

For the 10 knowledge questions given, the students showed a maximum knowledge of 91.76% and a minimum knowledge of 44.71% with an average knowledge of 65.49%.

**Table-2. QUESTIONWISE AWARENESS**

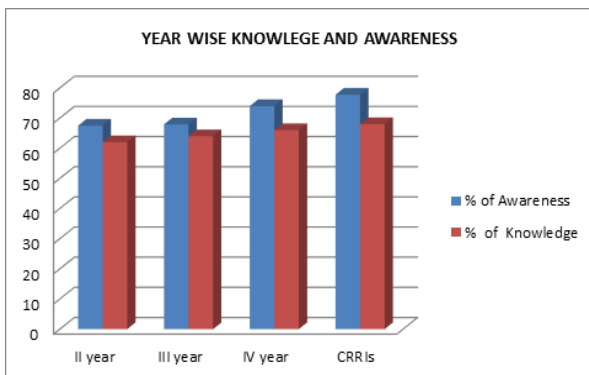
SL NO.	QUESTIONS	No. of students	% awareness
1	One of the following is a major risk factor for the occurrence of maximum adverse drug reactions	225	88.24
2	In India which Regulatory body is responsible for monitoring of ADR's?	160	62.75
3	Which of the following scales is most commonly used to establish the causality of an ADR?	115	45.09
4	Rare ADRs can be identified in the following phase of a clinical trial	175	68.63
5	Do you think reporting is a professional obligation for you?	179	70.19
6	Do you think reporting of adverse drug reaction is necessary?	244	95.69
<b>Total</b>		<b>183</b>	<b>71.76</b>

For the 6 awareness questions given, the students showed a maximum awareness of 95.69% and a minimum awareness of 45.09% with an average awareness of 71.76%.

**TABLE-3: YEAR WISE KNOWLEDGE AND AWARENESS**

Year of Study	Total No. Students	Total No. of Awareness Questions Asked	Percentage of Awareness	Total No. of Knowledge Questions Asked	Percentage of Knowledge
<b>II year</b>	80	6	67.5	10	62
<b>III year</b>	80	6	67.9	10	64
<b>IV year</b>	50	6	74	10	66
<b>CRRIs</b>	45	6	77.78	10	68

**FIGURE 1: YEAR WISE KNOWLEDGE AND AWARENESS**

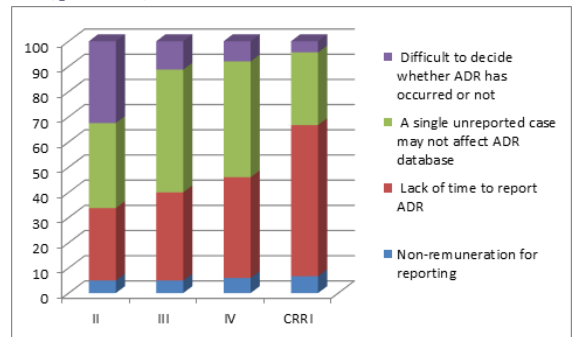


When yearwise awareness was considered, it was found that the CRRIs and IV years had more levels of awareness and knowledge compared to the II years and III years.

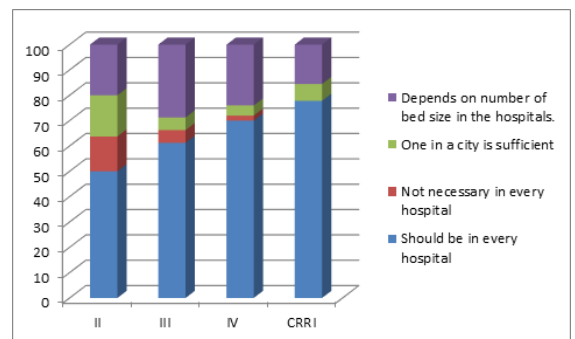
**Table-4 ASSOCIATION BETWEEN YEAR OF STUDY AND ATTITUDE**

Sl No	QUESTIONS	II year	III year	IV year	CRRIs	Chi Square Test
1	Do you think Pharmacovigilance should be taught in detail to healthcare professionals? yes	88.75	90	92	93.33	0.67
2	Have you anytime read any article on prevention of adverse drug reactions? yes	20	58.75	66	71.11	<0.001
3	Have you ever come across with an ADR? yes	27.5	40	52	68.89	<0.001
4	Have you ever been trained on how to report Adverse Drug Reaction (ADR)? Yes	21.25	27.5	34	64.44	<0.001

**FIGURE 2: FACTORS DISCOURAGING FROM REPORTING ADR (question 5)**



**FIGURE 3: OPINION ABOUT ESTABLISHING ADR MONITORING CENTRE IN EVERY HOSPITAL (question 6)**



Three questions that showed significant attitude ( $p < 0.001$ ) It was found that the CRRIs and IV years had more positive attitude of ADR reporting and pharmacovigilance compared to the II years and III years who had just entered the clinical phase stating that more positive attitude on pharmacovigilance comes along with clinical exposure to ADRs.

**DISCUSSION:**

Reporting of ADR is an essential component of Pharmacovigilance and is crucial to the safety surveillance of marketed medicinal products. Spontaneous ADR reporting is a vital method for detecting new safety issues related to drugs. ADR contribute significantly to morbidity and mortality in clinical practice with its associated economic consequence.<sup>6</sup>

Many studies have evaluated the knowledge of healthcare professionals and medical students about Pharmacovigilance. Response rate reported in our study was higher (85%) than that

reported in other studies. Response rate of (77%) was reported in another study carried out in prescribers.<sup>7</sup>

In our study the average knowledge of Pharmacovigilance among medical students was 65.49% and average awareness was 71.76%. When yearwise awareness was considered, it was found that the CRRIs and IV years had more levels of awareness and knowledge compared to the II and III years showing a gradual transition as students gained more knowledge and clinical exposure. This coincided with similar studies done in India which cited that resident doctors have highest scores in the excellent category of knowledge regarding pharmacovigilance which may be due to the clinical exposure and personnel experience in drug handling and managing adverse drug reactions.

Irrespective of the year of study, more than 60% of the students felt that ADR monitoring centre should be in every hospital. Majority of the II, III and IV year students felt that a single unreported case may not affect ADR database. This was the commonest among factors discouraging from reporting Adverse Drug Reactions. But 60 % CRRIs who spent more time with the patients in hospitals felt that they did not have time to report ADR. This correlated with findings of study done in North India which too showed under reporting of ADR in spite of 90% of the respondents considering it is important.<sup>8,9</sup>

In our study 91.2% of students had an attitude that Pharmacovigilance should be taught in detail to healthcare professionals. However the exposure to ADR, its knowledge and training to report ADR if met with one was significantly more among CRRIs compared to other students ( $p < 0.001$ ). This was higher than previous studies where only 78.30% of participated doctors agreed to keep ADR monitoring "Mandatory" and strongly believed that it will affect to patient safety directly or indirectly.<sup>10</sup>

The most important outcome of pharmacovigilance is the prevention of ADRs to pharmacotherapy. Pharmacovigilance programs have played a major role in detection of ADRs and banning of several drugs from the market<sup>(11)</sup>. However, under reporting of ADRs is one of the major problems associated with pharmacovigilance programs<sup>(12)</sup>. To overcome this problem we need a more positive knowledge, attitude and awareness among healthcare professionals regarding ADR monitoring and pharmacovigilance programmes. This can be done by conducting clinical meetings, CME programmes and distribution of ADR monitoring forms to the healthcare professionals etc.

Hence the present study was conducted to assess the knowledge, awareness and attitude of Pharmacovigilance among medical students.

Analysis of year wise knowledge and awareness showed that eventhough students gain basic knowledge and awareness of pharmacovigilance at II MBBS in pharmacology, their application and inturn both knowledge and awareness increases with clinical experience. Despite the good knowledge and awareness about Pharmacovigilance programme the actual reporting of adverse drug reaction is not adequate, may be because of their work load.

## CONCLUSION

The study identified the Knowledge, attitude and awareness of Pharmacovigilance among medical students of Chengalpattu Medical College, Tamilnadu. Our study showed positive knowledge and awareness among the students. The resident doctors had high scores compared to the final year MBBS students, which is due to their clinical exposure, handling drugs and managing adverse drug reactions in the hospital. The majority of them felt that ADR reporting and monitoring to be important, but only a few had ever reported an ADR.

From this study we note that the medical curriculum plays an vital role in knowledge of students. Also providing of adequate information about Pharmacovigilance during their second-year, would help in spreading adverse reaction reporting awareness, early detection, treatment, reduce the incidence and assist adverse reaction prevention and treatment. Pharmacologists have the primary responsibility of running a pharmacovigilance programme. Conducting CME programmes and clinical meetings will definitely improve the PVPI.

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