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## A CROSS-SECTIONAL QUESTIONNAIRE BASED STUDY ON KNOWLEDGE, ATTITUDE AND PRACTICE OF PHARMACOVIGILANCE AMONG SECOND PROFESSIONAL MBBS STUDENTS

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### Keywords:

ADR reporting, Attitude, Knowledge, Pharmacovigilance, Practice

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**ABSTRACT: Background:** Integrity is the cornerstone of pharmacovigilance. Underreporting is the main issue being faced by Pharmacovigilance programme. It is our moral duty as law-abiding citizens and medical professionals to report adverse drug reactions (ADRs) in order to protect patients' health. **Aim and Objective:** To study about the knowledge, attitude, practice of Pharmacovigilance among second professional MBBS students of SMCH. **Materials and Methods:** This is a questionnaire based cross sectional study. After gaining informed consent, 128 students were given the pre-tested, pre-validated questionnaire (knowledge 1–12, attitude 13–18, and practice 19–23) via Google form. Thirty minutes later the response was gathered. Microsoft Excel version 21 was used to statistically analyse the collected data. **Result:** Response rate was 100%. Of the participants, 97.7%, 81.3%, 85.9%, 87.5%, and 85.9% correctly answered questions about the definition of pharmacovigilance, the distinction between adverse drug reactions and adverse events, how to report adverse drug reactions, and the goals and techniques of pharmacovigilance. With regard to mindset, all students were aware of the importance and advantages of reporting ADRs. 98.4% of students were aware of SMCH having an ADR monitoring centre. About the practice, 98.4% had seen the ADR reporting form, 44.5% had dealt with ADRs, only 14.8% had reported ADRs, and 89.8% believed that ADRs should be reported if they were encountered. **Conclusion:** Students showed appreciable knowledge and attitudes regarding pharmacovigilance, but they applied them sparingly in real-world settings. As our future health care providers, students should get early sensitization through training programs.

**INTRODUCTION:** Pharmacovigilance is defined as “the science and activities relating to the detection, assessment, understanding, and prevention of adverse drug effects or any other possible drug related problems”<sup>1</sup>.

Medication therapy is a crucial component of medical supervision. Although it has numerous positive advantages, some of its main drawbacks are side effects and adverse drug reactions (ADRs).

ADR is defined by the World Health Organization (WHO) as “a response to a drug which is noxious and unintended, and which occurs at doses normally used in man”<sup>2</sup>. In India, under-reporting of ADR is a major drawback to patient care. India's ADR reporting rate is less than 1%, while the global rate is 5%<sup>3</sup>. A possible contributing factor

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to India's low reporting rate could be a lack of awareness and sensitivity to ADRs and pharmacovigilance. In order to guarantee medication safety and to identify and report adverse drug reactions (ADRs) on its own, India launched the National Pharmacovigilance Program in 2004<sup>4</sup>. Now known as the Pharmacovigilance Program of India, it has been running under the Central Drug Standard Control Organization's auspices since July 2010<sup>5</sup>.

The ADR monitoring centre (AMC) was established at Silchar Medical College in 2012. Despite 12 years of its existence, spontaneous reporting of ADRs is less among health care Professionals of this institute. The cause of under-reporting may be poor knowledge, improper attitude or lack of availability of reporting form or lack of time. However to improve ADR reporting culture among health care Professionals, the novice students should be trained at the outset of their career.

Medical undergraduates come in contact with clinical set up from 2<sup>nd</sup> year; so the aim of this study is to assess their Knowledge, attitude, practice on pharmacovigilance at the baseline. 2<sup>nd</sup> Professional MBBS students who are our future health care professionals, should be trained, sensitised and corrected to safeguard patient's health and to fulfil our objective of trusting the future doctors with our fellow human being's life.

## MATERIALS AND METHODS:

**Study Design:** This is a prospective observational cross-sectional questionnaire-based study.

**Study Centre:** Department of Pharmacology, Silchar Medical College, Silchar788014, Assam.

**Study Population:** Second Professional MBBS Students.

**Sample size:** 128 students.

**Ethical Consideration:** Written one to one consent was taken.

**Institutional Ethical Committee Clearance no:** SMC/18.849 Dated Silchar,the 23/11/2023

**Study Year:** 2023.

**Inclusion Criteria:** All the Second Professional MBBS students willing to participate and gave written informed consent.

**Exclusion Criteria:** All the Second Professional MBBS students not willing to participate.

**Study Tool:** Questionnaire containing 23 pre-tested, pre-designed, pre-validated questions distributed through Google form.

**Data Analysis:** All the data obtained through Google form were analysed using Microsoft Office 21.

**RESULT:** All the students (128) responded to the questionnaire distributed through Google form. So, the response rate was 100%.

**Knowledge:** There were 12 questions related to 'Knowledge'. The questions are shown in the **Table 1**.

**TABLE 1: THE NUMBER AND PERCENTAGE OF STUDENTS HAVING CORRECT OR INCORRECT 'KNOWLEDGE' HAVE BEEN SHOWN BELOW: (N=128)**

Questions regarding Knowledge	Correct Knowledge	Incorrect Knowledge
Definition of Pharmacovigilance	125(97.6%)	3(2.4%)
Meaning of ADR	124(96.9%)	4(3.1%)
Difference between ADR and Adverse event	104(81.2%)	24(18.8%)
Reporting of ADR	110(85.9%)	18(14.1%)
Full form of PVPI	124(96.9%)	4(3.1%)
Objectives of PVPI	112(87.5%)	16(12.5%)
Pharmacovigilance methods are	110(85.9%)	18(14.1%)
Location of IPC	99(77.3%)	29(22.6%)
Full form of CDSCO	117(91.4%)	11(8.6%)
Location of CDSCO Headquarters	56(43.8%)	72(56.2%)
Location of UMC	111(86.7%)	17(13.3%)
Celebration of Pharmacovigilance week	72(56.3%)	56(43.7%)

PVPI- Pharmacovigilance program of India, IPC-Indian Pharmacopoeia Commission, CDSCO-Central Drug Standard Control Organisation, UMC-Uppsala Monitoring Centre.

97.6%, 96.9% of the students knew the definition of Pharmacovigilance and meaning of ADR, while 18.8% students did not know the difference between ADR and adverse event. 14.1% students did not know 'by whom ADR can be reported'. 96.9% of the students knew about PVPI. 12.5% students did not know about the objective of PVPI.

14.1% of the students did not know about Pharmacovigilance method. 22.6% students did not know the location of IPC. 91.4% students knew the full form of CDSCO. 56.2% students did not know CDSCO headquarters' location. 13.3% students did not know location of UMC. 43.7% students did not know about Pharmacovigilance week.

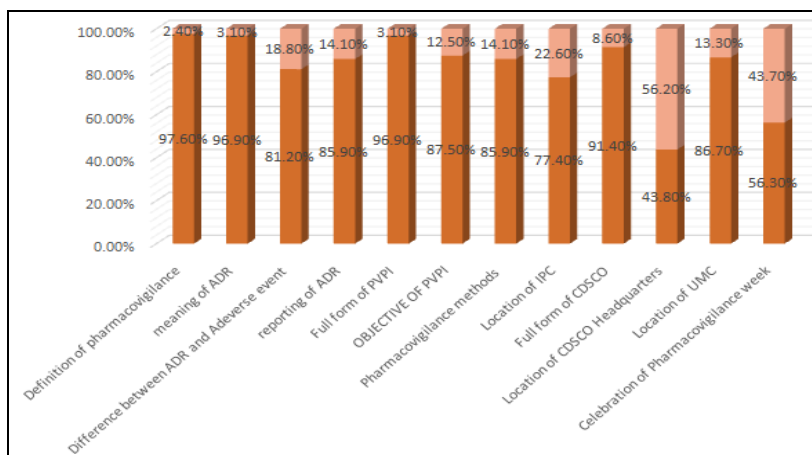


FIG. 1: DEPICTING RESPONSES OF STUDENTS REGARDING 'KNOWLEDGE' ON PHARMACOVIGILANCE

**Attitude:** There were 6 questions related to 'Attitude' of Pharmacovigilance shown in the **Table 2**.

TABLE 2: THE NUMBER AND PERCENTAGE OF STUDENTS HAVING POSITIVE OR NEGATIVE 'ATTITUDE' TOWARDS PHARMACOVIGILANCE HAVE BEEN SHOWN IN TABLE BELOW. (N=128):

Questions	Positive Response	Negative Response
AMC at Silchar Medical College	126(98.4%)	2(1.6%)
Role of ADR monitoring centre	114(89.1%)	14(10.9%)
ADR reporting is necessary	128(100%)	0
ADR reporting benefits both health care professionals and patients	128(100%)	0
Second year MBBS graduates could play a role in ADR reporting	123(96.1%)	5(3.9%)
Have been trained on ADR reporting	126(98.4%)	2(1.6%)

98.4% students gave a positive response about Silchar Medical College and Hospital having a ADR monitoring centre. 89.1% gave positive response regarding role of ADR monitoring centre. All of the students gave positive response regarding

necessity and benefits of ADR reporting. 96.1% students gave positive response regarding them playing role in ADR reporting while 98.4% students gave positive response that they have been trained on ADR reporting.

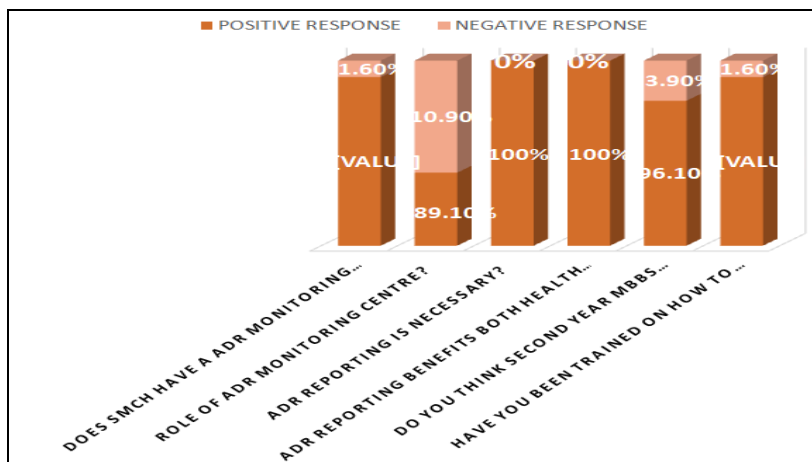


FIG. 2: DEPICTING RESPONSES OF STUDENTS REGARDING 'ATTITUDE' ON PHARMACOVIGILANCE

**Practice:** There were 5 questions related to 'Practice' of Pharmacovigilance shown in **Table 3**.

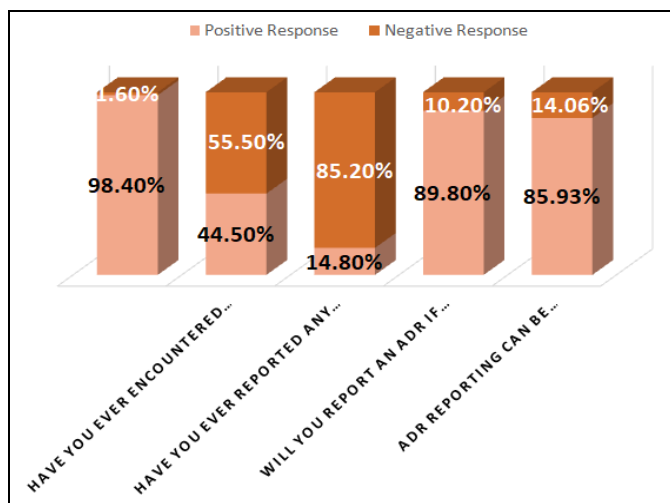
**TABLE 3: THE NUMBER AND PERCENTAGE OF STUDENTS WHO GAVE RESPONSE TO THE QUESTIONS ON 'PRACTICE' OF PHARMACOVIGILANCE, HAVE BEEN SHOWN IN BELOW TABLE (N=128):**

Questions	Yes	No
Have you ever seen ADR reporting form	126(98.4%)	2(1.6%)
Ever encountered with ADR related to any drug	57(44.5%)	71(55.5%)
Ever reported any ADR	19(14.8%)	109(85.2%)
Will you report an ADR if encountered	115(89.8%)	13(10.2%)
ADR reporting can be increased	110(85.9%)	18(14.1%)

98.4% students have affirmed that they have seen ADR reporting form while 55.5% students affirmed that they have never encountered with ADR related to any drug. Only 14.8% students have ever reported any ADR while 89.8% students confirmed that they would report ADR if encountered.

Question no. 23 seeks information about how the reporting can be increased. Among 4 options given on questionnaire, 110 students marked 'all of the above' which contained the options as-a) promoting awareness programme and training on Pharmacovigilance.

1. Making ADR reporting process easier.
2. All of the above.
3. None of the above.



**FIG. 3: DEPICTING RESPONSES OF STUDENTS REGARDING 'PRACTICE' OF PHARMACOVIGILANCE**

**DISCUSSION:** With the exception of the questions about "CDSCO Headquarters" and "pharmacovigilance week," the students' knowledge of pharmacovigilance is good. 43.7% did not know about "Pharmacovigilance week," and 56.2% were unaware of CDSCO Headquarters.

Students' "attitude" toward pharmacovigilance is commendable. All students concurred that ADR reporting is important and beneficial for patients as well as healthcare providers.

Just 14.8% of students have ever reported an ADR, and 44.5% of them lack experience in doing so. Even yet, 89.8% of them promised to report any ADRs they encountered.

Our study is different from that of Meher *et al.*, who discovered that although students had the right attitude toward pharmacovigilance, they lacked the knowledge and skills to report adverse drug reactions<sup>6</sup>.

Our research supports the findings of a study by Narsimha Rao *et al.* on the KAP of pharmacovigilance among undergraduate MBBS students, which likewise revealed that students had a good understanding of and attitude toward pharmacovigilance but did not practice reporting adverse drug reactions<sup>7</sup>.

The results of a study by Singh *et al.* from Guwahati Medical College and Hospital, Guwahati, Assam, lend support to our investigation. They found that while UG and PG students lacked experience in ADR reporting, they both have sufficient knowledge and a commendable approach toward pharmacovigilance. Further investigation revealed that time, motivation, and information scarcity were the main causes of underreporting. They proposed that regular CMEs and appropriate training could boost ADR reporting, and we concur with them<sup>8</sup>.

Once more, we concur with the research findings of R. *et al.*, which indicated that there is a discrepancy between the real knowledge and attitude toward pharmacovigilance and the actual practice of reporting adverse drug reactions. The highlighted

factors included not knowing where to submit an ADR, and the healthcare providers' "priority" on "patient care" over ADR reporting. This emphasizes how important it is for aspiring doctors to have regular, thorough, and continuous pharmacovigilance workshops and education programs<sup>9</sup>.

**Limitation:** Because we only included second-year professional MBBS students in our study, we were unable to evaluate the knowledge, attitudes, and practices of other medical professionals regarding pharmacovigilance. There is not a complex or sophisticated statistical analysis in our work.

**Strength:** The last question of the questionnaire offers suggestions for how to enhance ADR reporting. In response, 85.9% of students said they agreed that different training programs should be held and that students doing their second professional MBBS should attend them.

**CONCLUSION:** Beginning with the second year of the MBBS program, we have a fantastic chance to better equip future practitioners with a better understanding of ADR reporting. So, through a variety of training programs on pharmacovigilance, ADR reporting should be taught and skills should be fostered among undergraduates starting from the start of clinical exposure.

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