

# KNOWLEDGE, ATTITUDE AND PRACTICES OF PHARMACY STUDENTS ON ADR REPORTING IN INDIA

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## ABSTRACT

Drug therapy is an essential part of medical treatment. It has a lot of advantages, but it also has a lot of disadvantages, such as adverse drug reactions (ADRs). ADRs are a worldwide public health concern. In its most severe form, it can result in hospitalizations, morbidity, and death. This study aims to assess the knowledge and attitudes and practices of pharmacy students on ADR reporting in India.

A cross-sectional descriptive, online questionnaire-based survey on ADR reporting practices was conducted among pharmacy students of various pharmacy colleges across India. This study was conducted from April to May 2022. A total of 387 responses were collected from pharmacy students. The data was coded, entered and analyzed using SPSS Version 21. The comparison of the knowledge, attitude and practices of pharmacy students on ADR reporting across various pharmacy colleges in India was analyzed using Mann Whitney U test. The association between demographics of pharmacy students and their KAP was assessed using Chi-square test.

There was no statistically significant difference in the knowledge, attitude and practices of pharmacy students across India.

The knowledge of pharmacy students on ADR reporting was comparatively good across India.

However, this higher knowledge scores failed to influence their attitude and reporting practices. Therefore, there is a room for improvement in the reporting of ADRs.

**Keywords:** Adverse Drug Reactions, Knowledge, Pharmacovigilance, Pharmacy students, Questionnaire, Reporting practices

## INTRODUCTION

Every day, a large number of drugs are introduced onto the market around the world; nevertheless, due to a lack of understanding, the safety of medicines remains a key worry for many population groups. [1]. One of the most serious issues with medicines are adverse drug reactions. ADRs are the cause of many hospital admissions. The World Health Organization (WHO) defines an ADR as “a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or the modification of physiological function” [2]. According to ICH GCP, an adverse event (AE) is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment [3]. According to the American Society of Health-System Pharmacists (ASHP), adverse drug reactions (ADRs) can cause temporary or permanent harm, disability, or death, and may necessitate discontinuing the drug, changing the drug therapy, modifying the dose, hospitalization, prolonged stay in a healthcare facility, supportive treatment, significantly complicating diagnosis, or negatively affecting prognosis [6]. Drug prescriptions should always be made with caution and a favorable risk/benefit ratio in mind. According to research, in India and other highly developed industrialized countries, 0.2 % to 24 % of patients with ADRs are referred to hospitals. ADR has a huge impact on health-care costs as well [7]. Traditionally, a pharmacist's responsibility was restricted to the manufacture and administration of medications recommended by a physician. The pharmacist's responsibility has recently evolved to include other parts of patient care. Reporting ADRs, improving patients' health, and achieving a positive economic outcome are all part of these duties. Pharmacists can help to improve ADR reporting and pharmacovigilance by raising the quantity and quality of reports submitted [8].

The most extensively utilized and cost-effective surveillance strategy for ADRs is spontaneous (yellow card) reporting, which is the cornerstone of drug safety is monitoring in clinical practice. It finds risk variables that predispose to medication toxicity and explores causality by detecting previously undiscovered adverse events and identifying risk factors that predispose to drug toxicity. It aids risk-benefit evaluations and comparisons within therapeutic categories, in addition to recognizing drug safety issues. Intrinsic characteristics such as knowledge, attitude, and practice can aid in determining how pharmacists interact with patients and other healthcare professionals, as well as developing measures to encourage pharmacists to report adverse drug reactions (ADRs). A few studies conducted in India revealed that the majority of health-care practitioners had above-average pharmacovigilance knowledge and a favorable attitude toward the importance of ADR reporting. [9]. A lack of expertise with pharmacovigilance and ADR reporting has been linked to healthcare personnel underreporting of ADRs. Healthcare students may not understand the significance of post-marketing adverse drug reactions (ADRs) and may not have gained appropriate knowledge and skills to recognize and report ADRs during their education. Children, pregnant women, elderly and the diseased are among the most vulnerable populations to ADRs. Through pharmacovigilance programmes focused on the specific drug, adequate information about drug safety and side effects should be communicated to this vulnerable population [11]. Pharmacists should offer service in Pharmacovigilance for drug safety use and superior patient care in addition to upgrading their dispensing pharmacy by delivering cognitive pharmaceutical services. [12].

## MATERIALS AND METHODS

A cross-sectional, descriptive, online questionnaire-based survey on KAP of

pharmacy students on ADR reporting across India was conducted between April - May 2022. Those who did not consent to participate in the study were excluded. The sample size was calculated using the Raosoft sample size calculator. The confidence level was 95%, population size – 20000, response distribution - 50 %. The minimum recommended sample size hence obtained was 377.

### Ethical consideration

The study was approved by the Institutional Review Board of Government Medical college and hospital, Ooty.

### Data collection

A semi-structured questionnaire was prepared by reviewing relevant literature [1,6,7,9] which was then face validated by a team of 3 pharmacists followed by internal consistency check using Cronbach's alpha that yielded a score of 0.85. This self-administered questionnaire was then distributed to pharmacy students as google forms after obtaining their informed consent. The questionnaire included a total of 31 questions: Demographics (5), Knowledge (11), Attitude (10) and Reporting practices (10). Knowledge and practices questions are closed ended with

yes/no options, objective type questions and wherever additional information is required open ended questions are used. Each correct response was indicated with 1 point while the incorrect response was allotted a score of 0 points. A 5-point Likert scale was used to respond to attitude questions. Strongly disagree (1 point), disagree (2 points), neither agree nor disagree (3 points), agree (4 points), and strongly agree (5 points) are the five options.

The total scores for knowledge, attitude and dispensing practices were calculated as follows:

$$\% \text{ (knowledge/attitude/practice)} = \frac{\text{calculated (knowledge/attitude/practice) score} \times 100}{\text{expected (knowledge/attitude/practice) score}}$$

The scores were graded as follows: <50% - poor, 50–70% - fair and  $\geq 70\%$  - good.

## RESULTS

A total of 387 responses were collected from pharmacy students across India. The demographic characteristics of pharmacy students are summarized below (Table 1).

**Table 1: Demographic characteristics of Pharmacy students across India**

Variables	No. of respondents(n=387)	% of respondents
<b>Age (Years)</b>		
• 18-20	32	8.3%
• 21-23	310	80.1%
• 24-26	45	11.6%
<b>Gender</b>		
• Male	170	43.9%

• Female	217	56.1%
<b>Course</b>		
• B Pharm	166	42.9%
• Pharm D	186	48.1%
• M Pharm	35	9%
<b>Year</b>		
• First Year		
• Second Year	23	5.9%
• Fourth Year	12	3.1%
• Fifth Year	234	60.5%
• Sixth Year	69	17.8%
	49	12.7%

Response on Knowledge of pharmacy students across India are summarized below (Table 2)

**Table 2: Response on Knowledge of pharmacy students across India.**

<b>Knowledge Query(n=387)</b>	<b>Correctresponse n [%]</b>	<b>Incorrectresponse n [%]</b>
1. Do you understand what "adverse drug reaction" means?	383[99.0]	4[1.0]
2. Do you know what Pharmacovigilance is for?	374[96.6]	13[3.4]
3. Do you know where to report ADR in India?	215[55.6]	172[44.4]
4. Are you aware of the first steps to take while dealing with a major ADR?	326[84.2]	61[15.8]

5. Are you aware of the information that must be included on an ADR reporting form?	328[84.8]	59[15.2]
6. Do you know the difference between adverse drug reactions (ADRs) and adverse drug events (ADEs)?	333[86.0]	54[14.0]
7. What type of ADR comes under Type A?	317[81.9]	70[18.1]
8. What type of ADR comes under Type B?	237[61.2]	170[38.8]
9. Who can report an ADR in India?	308[79.6]	79[20.4]
10. Which ADRs should be reported?	327[84.5]	60[15.5]
11. Which form is used in India to report ADR?	297[76.7]	90[23.3]

Response on Attitude of pharmacy students across India are summarized below (Table 3)

**Table 3: Response on Attitude of Pharmacy students across India**

Attitude Query(n=387)	Strongly Agree n [%]	Agree n [%]	Neutral n [%]	Disagree n [%]	Strongly Disagree n [%]
1. Do you believe pharmacy students could help with adverse drug reaction reporting?	266[68.7]	112[28.9]	7[1.8]	1[0.3]	1[0.3]
2. Do you believe ADR forms are difficult to complete?	57[14.7]	91[23.5]	136[35.1]	81[20.9]	22[5.7]
3. Do you believe that disclosing ADRs is beneficial to both patients and doctors?	170[43.9]	134[34.6]	57[14.7]	23[5.9]	3[0.8]
4. Do you believe that major adverse drug reactions inspire pharmacists to report them to the appropriate authorities?	176[45.5]	163[42.1]	40[10.3]	7[1.8]	1[0.3]

5. Do you believe ADR reporting must be strictly followed for practicing pharmacists?	219[56.6]	135[3 4.9]	24[6.2]	8[2.1]	1[0.3]
6. Will you report an ADR when you come across one?	213[55.0]	134[3 4.6]	34[8.8]	4[1.0]	2[0.5]
7. Do you believe you are well prepared to disclose any ADRs in your future practice based on your current knowledge?	151[39.0]	149[3 8.5]	74[19.1]	10[2.6]	3[0.8]
8. Do you believe that new drugs should be closely monitored?	245[63.3]	111[2 8.7]	24[6.2]	6[1.6]	1[0.3]
9. Do you believe pharmacy students will be able to report adverse drug reactions(ADRs)?	200[51.7]	152[3 9.3]	31[8.0]	3[0.8]	1[0.3]
10. Do you believe that ADR reporting is not widely promoted by appropriate authorities in India?	122[31.5]	154[3 9.8]	92[23.8]	16[4.1]	3[0.8]

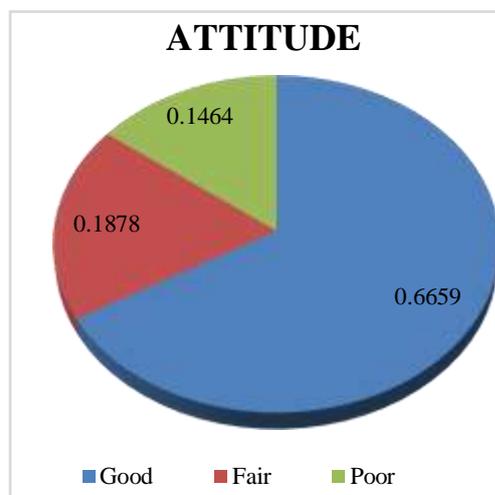
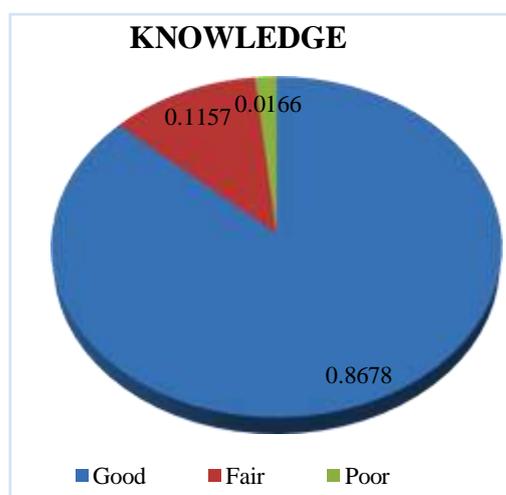
Response on Practice of pharmacy students across India are summarized below (Table 4)

**Table 4: Response on practice of pharmacy students across India.**

Practice Query(n=387)	Correct response n [%]	Incorrect response n [%]
1. Do you come across ADRs in your hospital visit?	215[55.6]	172[44.4]
2. Have you ever received training on how to report an ADR?	186[48.1]	201[51.9]
3. Have you filled out an ADR reporting form?	134[34.6]	253[65.4]
4. Have you ever reported ADR to the PV centre?	98[25.3]	289[74.7]
5. Have you ever attended a Pharmacovigilance awareness programme?	221[57.1]	166[42.9]
6. Have you ever counselled patients about the likelihood of ADRs and instructed them to share their ADR information with their doctor?	173[44.7]	214[55.3]
7. Have you ever read an article about how to avoid ADR?	230[59.4]	157[40.6]
8. Have you ever assessed the causality of ADRs?	173[44.7]	214[55.3]
9. Have you ever faced any difficulties in reporting ADRs?	132[34.1]	255[65.9]
10. Do you maintain records of ADR?	157[40.6]	230[59.4]

The total score for knowledge, attitude and practices were calculated separately for all pharmacy students. The percentage knowledge,

attitude, and practices of pharmacy students on ADR reporting are portrayed (figure 1a, 1b and 1c) respectively.



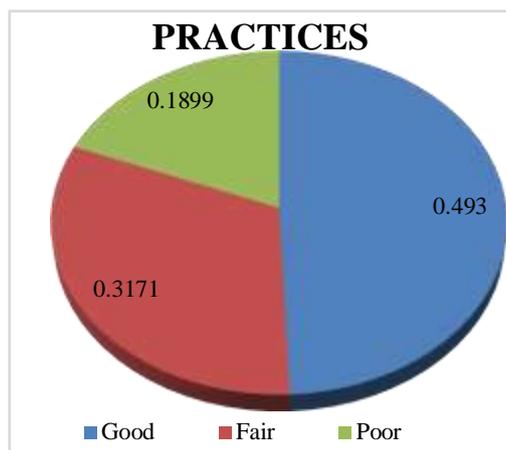


Figure 1a. Knowledge percentage by pharmacy students across India. Figure 1b. Attitude percentage by pharmacy students across India. Figure 1c. Knowledge percentage by pharmacy students across India.

Analysis of the data in MS Excel showed a skewed distribution. Therefore, Mann Whitney U test was used to determine the differences in Knowledge, Attitude and Practices of pharmacy

students on ADR reporting across India. The results obtained are shown below (Table 5).

**Table 5. Comparison of Knowledge, Attitude and Practices of pharmacy students on ADR reporting across India using Mann Whitney U test.**

Null Hypothesis	Test	Significance	Decision
The distribution of knowledge total score is the same across different categories of college	Independent samples Mann-Whitney U test	0.386	Retain the null hypothesis
The distribution of attitude total score is the same across different categories of college	Independent samples Mann-Whitney U test	0.780	Retain the null hypothesis
The distribution of practices total score is the same across different categories of college	Independent samples Mann-Whitney U test	0.195	Retain the null hypothesis

\* $p$  value < 0.05 is considered to be statistically significant

From the above table, there is no statistically significant difference in the knowledge, attitude and reporting practices of pharmacy students across various pharmacy colleges in India. The overall Knowledge, Attitude and Reporting practices pharmacy students on ADR reporting across various pharmacy colleges in India is

given below in figure 5. College 10, 11 and 15 have higher average knowledge scores compared to other colleges.

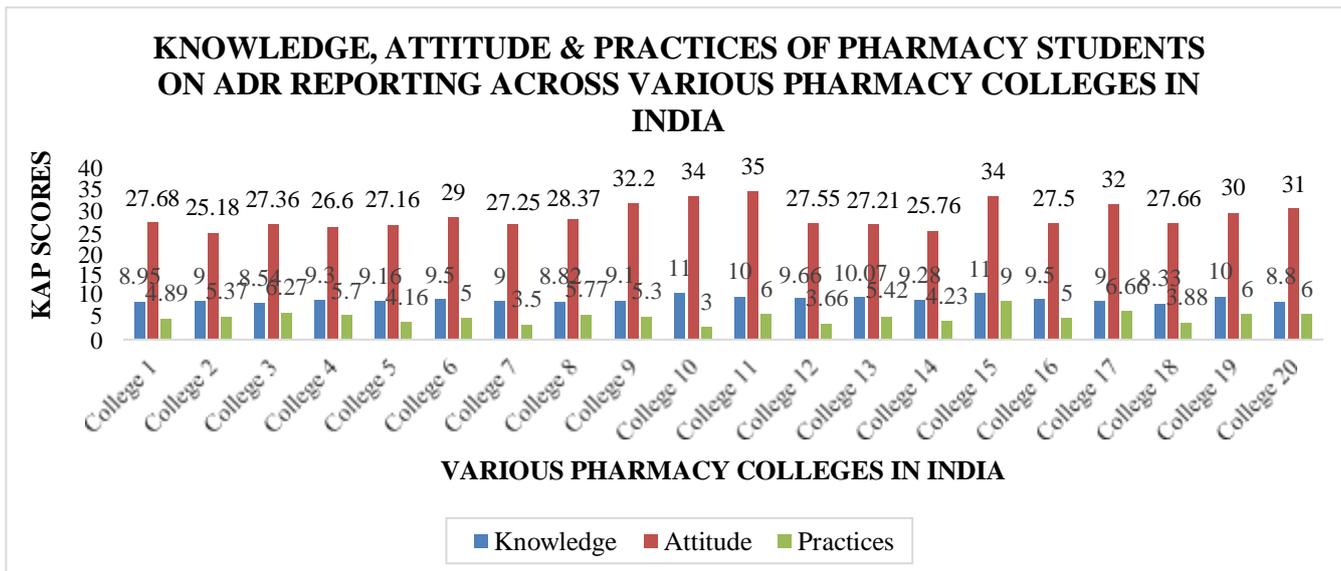


Figure 5. Average knowledge, attitude, and reporting practices on ADR reporting by pharmacy students across various pharmacy colleges in India.

Association between demographics and KAP of pharmacy students across India.

The association between demographics and knowledge of pharmacy students using Chi square test is depicted (Table 6).

Table 6. Association between demographics and KAP of pharmacy students.

Demographic characteristics	Value	df	Significance (2-sided)
Age	8.754 <sup>a</sup>	18	0.965
Gender	11.154 <sup>a</sup>	9	0.265
Course	21.122 <sup>a</sup>	12	<b>0.049*</b>
Year	38.912 <sup>a</sup>	24	<b>0.028*</b>

The association between demographics and attitude of pharmacy students using Chi

square test is depicted (Table 7).

Table 7. Association between demographics and KAP of pharmacy students across India.

Demographic characteristics	Value	df	Significance (2-sided)
Age	81.607 <sup>a</sup>	58	0.022
Gender	27.184 <sup>a</sup>	29	0.562
Course	49.446 <sup>a</sup>	44	0.265
Year	74.551 <sup>a</sup>	20	0.000

The association between demographics and

practices of pharmacy students using Chi

square test is depicted below (Table 8).

**Table 8. Association between demographics and KAP of pharmacy students across India.**

Demographic characteristics	Value	df	Significance (2-sided)
Age	26.522 <sup>a</sup>	20	0.149
Gender	8.916 <sup>a</sup>	10	0.540
Course	24.086 <sup>a</sup>	20	0.239
Year	79.255 <sup>a</sup>	40	0.000

**Table 9. Barriers to ADR reporting and recommendations to overcome them**

Barriers to ADR reporting	Recommendations to overcome barriers
Lack of knowledge about the ADR monitoring system and practices.	Pharmacy students should be educated about the ADR monitoring system and practices to actively participate in the documentation.
Lack of confidence in reporting ADR.	Encourage pharmacy students to report ADRs.
Many of them had no idea how to fill out an ADR reporting form.	Attending ADR reporting simulation activities.
Lack of time constraints.	Pharmacy students should set aside some time to complete the forms.
Not familiar with the ADR reporting system.	Familiarize pharmacy students with the PvPI, CDSCO and WHO websites, circulating ADR reporting promotional materials, attending PvPI webinars.

## DISCUSSION

ADRs are a serious public health issue that result in higher mortality, morbidity and expenses, as well as more hospital admissions and duration of stay. [5]. This study aims to assess the knowledge, attitude, and practices (KAP) of ADR reporting among pharmacy students in India.

In our study we have found that there is an association between year and course with that of KAP, since it is statistically significant with  $p$  value  $< 0.05$ . We have also observed that College 10, 11, 15 have good responses to the overall KAP in comparison with other colleges. We could also observe that ADR reporting practices were poor among the pharmacy students who were involved in our study. The reasons were things like lack of knowledge, time, confidence and not being familiar with

reporting practices. A similar study was conducted by Upadhyaya et al, have concluded that reporting of ADR was infrequent among medical postgraduates.[7] From our study, we observed most of the respondents had a good knowledge level [86.78%] and a considerable proportion had a poor knowledge level [1.66%]. In terms of attitudes and practices, only 66.59% and 49.30% had good attitudes and practices, respectively, while 14.64% and 18.99% had poor attitudes and practices. This may be due to inadequate practical exposure of pharmacy students to ADR reporting in clinical settings.

## CONCLUSION

This study showed that pharmacy students from states in South India have a better knowledge compared to the Rest of India. The knowledge

on ADR reporting by pharmacy students was comparatively good across India. However, these higher knowledge scores failed to influence their attitude and reporting practices. Therefore, there is room for improvement in the reporting of ADRs. Pharmacy students are discouraged from reporting ADRs due to a lack of knowledge, time, training, and confidence. Relevant awareness campaigns such as Pharmacovigilance awareness programmes should be intended to improve ADR reporting which is likely to benefit pharmacy students.

### Limitations

- Inability to reach out to pharmacy students in all states of India.
- Low willingness to participate in the study.

### Future Directions

- Conduct a pre-post interventional study including an awareness program on ADR reporting.
- Encourage pharmacy students to report ADRs.

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