VOLUME - 13, ISSUE - 08, AUGUST - 2024 • PRINT ISSN No. 2277 - 8160 • DOI : 10.36106/gjra

Original Research Paper

General Medicine

A QUESTIONNAIRE-BASED STUDY ON KNOWLEDGE, ATTITUDE, AND PRACTICE OF INTERNS AND POSTGRADUATES ABOUT ADVERSE DRUG REACTIONS REPORTING IN A TERTIARY CARE HOSPITAL, TELANGANA.

Abdul Wasay Mohammed*	Intern, Deccan College Of Medical Sciences, Santhosh Nagar - 500058, Telangana, India. *Corresponding Author
Fateen Shareef	Intern, Deccan College Of Medical Sciences, Santhosh Nagar - 500058, Telangana, India.
Azeeza Tabassum	Intern, Deccan College Of Medical Sciences, Santhosh Nagar - 500058, Telangana, India.
Azha Fatima	Mbbs Final Year, Kamineni Academy Of Medical Sciences And Research Center, Lb Nagar - 500068, Telangana, India.
Abdul Basith	3rd Year Mbbs, Deccan College Of Medical Sciences, Santhosh Nagar - 500058, Telangana, India.

ABSTRACT

Background: Adverse drug reactions (ADRs) must be reported by medical professionals to prevent drug-related tragedies. The pervasive underreporting of ADRs is problematic. Increased awareness helps identify and prevent ADRs. It's crucial to educate young healthcare workers on ADR reporting in clinical practice. Our study aims to analyze interns' and postgraduates' ADR reporting knowledge, attitude, and practice. **Methods:** This research, was carried out on medical interns and postgraduates at a tertiary care hospital in Telangana. It is a questionnaire-based study of 110 medical students. The study participants were given a series of standard questions on knowledge, attitude, and practice on ADR reporting. Before the study ethical letter was acquired. SPSS software was used to evaluate the collected data, and a p value of $< 0.001^*$ was considered significant. **Results:** Out of 110 study participants, most participants were from the 21-30 years of age group (48.3%) with a male predominance (67.3%). Interns (65.5%) were in the majority than the postgraduates (34.5%) The study indicated that the overall knowledge ($_2 = 55.296$, $p = 0.001^*$), attitude ($_2 = 64.873$, $p = 0.001^*$), and practice ($_2 = 88.148$, $p = 0.001^*$) of study participants were statistically significant. **Conclusions:** Interns and postgraduates are aware of ADR reporting, but interns lack practice and postgraduates lack attitude. Most participants felt reporting adverse drug responses was their top responsibility, along with patient safety. Education and sensitization of prospective medical professionals on ADR reporting can improve patient compliance and prevent tragedies.

KEYWORDS : Adverse Drug Reactions (ADRs), Interns, Postgraduates, Knowledge, Attitude, Practice.

INTRODUCTION

Medications will combat a range of illnesses or conditions and significantly alleviate suffering. Although drugs have beneficial benefits, they can sometimes cause adverse drug reactions. Adverse Drug Reaction refers to harmful and unintentional alterations that happen when patients are given dosages often used for preventing, diagnosing, or treating diseases, or for modifying normal bodily functions.[1] The adverse drug reactions (ADRs) can range from mild to serious and, to a certain degree, may result in organ deformities. ADRs caused substantial rates of death and illness worldwide, leading to increased spending and economic decline for patients in the healthcare industry.[2]

The ADR reporting from medical professionals and consumers is highly advantageous for generating alerts on unforeseen adverse drug effects to ensure drug safety.[3] The objective of ADR reporting is to decrease patient mortality and severe outcomes, minimize hospital readmissions and total expenditures, prevent future ADR occurrences, and enhance the quality of patient treatment.[4] ADR monitoring and reporting systems offer valuable data on the effectiveness and safety of medicines They also help to implement risk-management strategies, prevent anticipated side effects, and assist in determining the occurrences of ADR.[5] Furthermore, it enhances the understanding of adverse drug reactions (ADR) and provides education to both the healthcare staff and patients on ADR. Healthcare professionals (HCPs) such as medical physicians, nurses, and pharmacists have the responsibility of finding, recording, reporting, and avoiding adverse drug reactions (ADRs) in their regular clinical practice.[6]

To improve understanding of ADRs, it is necessary to establish a meticulously structured reporting system that includes an ADR database, which should be managed by highly skilled physicians. This will aid us in ensuring improved patient adherence and safety with both novel and existing medications. The purpose of this study was to assess the Knowledge, Attitude, and Practice of medical interns and post-graduates regarding the reporting of adverse drug reactions at a tertiary care teaching hospital, in Telangana.

METHODS

This is a questionnaire-based cross-sectional study, conducted from June 2023 to December 2023 at Deccan College of Medical Sciences (DCMS). The study had 110 participants, consisting of male and female individuals, including medical interns and postgraduates, respectively. Upon receiving consent from the participants, a questionnaire was distributed, with clear instructions to select replies based on their knowledge, attitude, and practice.

Study design

The questionnaire was created to assess the comprehension of interns and postgraduates on the reporting of Adverse Drug Reactions, including their knowledge, attitude, and practice in this area. The assessment had a total of 21 questions, divided into 3 distinct portions as outlined below. The Sociodemographic characteristics, knowledge, attitude, and practice of the participants, in that order. The selected replies by the study participants were verified for precision and organized using Microsoft Office software.

Statistical analysis

The data was examined with the SPSS software. Data is represented in tabular and graphical formats, displaying frequencies (n) and percentages (%). The chi-square test ($\chi 2$)

was employed for data comparisons, with a significance level of $p \leq 0.05$*.

RESULTS

In the present study, it was observed that among the study participants, the 21-30 years age group was predominant (83.6%) and male gander was in the majority (67.3%), respectively. Interns participated more (65.5%) than postgraduates (34.5%). [Figure 1,2,3]

In the essential knowledge questions section, it was observed that most of the correct answers were for the question, 'What is the primary objective of pharmacovigilance?', (78.2%), followed by the question, 'Which regulatory organization oversees the monitoring of Adverse Drug Reactions (ADRs) in India?', (71.8%), respectively. [Table 1]

In the section related to the attitude of the study participants, it was observed that 86.4% of participants strongly agreed that an ADR monitoring center be established in every hospital, and 74.5% strongly agreed ADR reporting is necessary. 47.3% strongly agreed that one report can make a difference 75.5% strongly agreed on pharmacovigilance teaching importance for healthcare professionals and 88.2% strongly agreed that Pharmacovigilance practice can improve patients' quality of life, respectively. [Table 2]

On examining the practicing behavior of participants, it was revealed that 58.2% said they have an ADR monitoring center in their institute, 61.8% there is no daily frequency of encountering patients with ADR, 70% agreed on reporting ADR on encounter, 73.6% haven't submitted ADR reports. [Table 3]

Insufficient time provided to report ADR was selected by 66.4% of participants when asked regarding the reason that discourages them from reporting Adverse Drug Reactions. [Figure 4]

Relationship between interns and postgraduates about Adverse Drug Reactions reporting

There was an observation that interns and postgraduates both seem to have more knowledge than postgraduates, with a Chi-square test value of 55.296 and a p value of 0.001*. Attitude was good in interns and postgraduates with a Chi-square value of 64.873 and a p value of 0.001*. The practice of interns was less when compared to postgraduates with a Chi-square value of 88.148 and a p value of 0.001*, respectively. [Table 4].

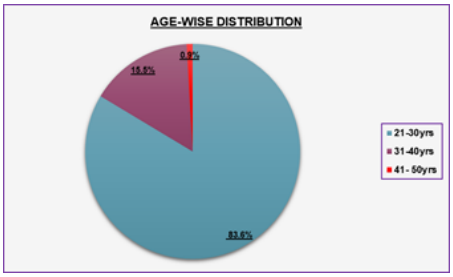

Figure 1: Age-wise distribution

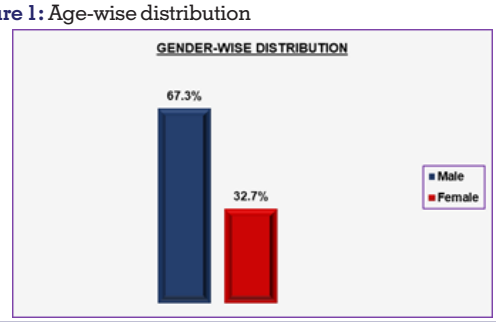

Figure 2: Gender-wise distribution

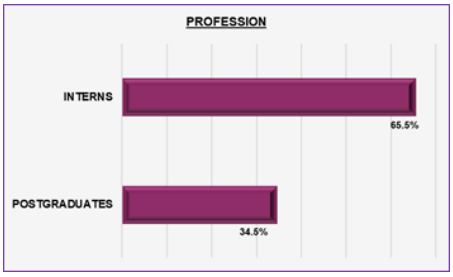

Figure 3: Profession of the participants

Table 1: - Examining The Knowledge Of Participants

Essential questions of knowledge	Correct answer	Participants' Answers in frequency (n)	Participants' Answers in Percentage (%)
1.What is the primary objective of pharmacovigilance? To ascertain the safety of drugs.	True	True-86 False-24	78.2% 21.8%
2.What is the consequence of a serious adverse event? Mortality.	True	True-56 False-54	50.9% 49.1%
3.During what period can rare adverse drug reactions (ADRs) be identified? Post-marketing surveillance (Monitoring and analysis of a product's safety and effectiveness after it has been approved and made available to the public.)	True	True-76 False-34	69.1% 30.9%
4.In India, a significant adverse event must be notified to the regulatory agency within what timeframe? Within 14 calendar days.	True	True-59 False-51	53.6% 46.4%
5.Which regulatory organization oversees the monitoring of Adverse Drug Reactions (ADRs) in India? Central Drugs Standard Control Organization (CDSCO).	True	True-79 False31	71.8% 28.2%
6.What is the specific ADR reporting form utilized in India for reporting adverse drug reactions (ADRs)? White form	True	True-58 False-52	52.7% 47.3%
7.How can ADR be reported? Medical professionals including doctors, nurses, and pharmacists	True	True-61 False-49	55.5% 44.5%

Table 2: - Examining The Attitude Of Participants

	Frequency (n=110)	Percentage (%)
1.ADR monitoring center be established in every hospital?		
Strongly agree	95	86.4%
Agree	11	10%
Neutral	04	3.6%
Disagree	00	0%
Strongly disagree	00	0%
2.In your opinion, is it necessary to report ADR?		
Strongly agree	82	74.5%

Agree	20	18.2%
Neutral	08	7.3%
Disagree	00	0%
Strongly disagree	00	0%
3.Do you think that one report can make a difference?		
Strongly agree	52	47.3%
Agree	38	34.5%
Neutral	00	0%
Disagree	20	18.2%
Strongly disagree	00	0%
4.Do you think Pharmacovigilance should be taught in detail to healthcare professionals?		
Strongly agree	83	75.5%
Agree	13	11.8%
Neutral	09	8.2%
Disagree	05	4.5%
Strongly disagree	00	0%
5.Pharmacovigilance activities can help in reducing mortality and morbidity.		
Strongly agree	77	70%
Agree	26	23.6%
Neutral	07	6.4%
Disagree	00	0%
Strongly disagree	00	0%
6.Do you think, Pharmacovigilance practice can bring improvement in the quality of life?		
Strongly agree	97	88.2%
Agree	13	11.8%
Neutral	00	0%
Disagree	00	0%
Strongly disagree	00	0%

Table 3: - Examining The Practicing Behavior Of Participants

	Frequency (n=110)	Percentage (%)
1.Does your institution have an ADR monitoring center?		
Yes	64	58.2%
No	46	41.8%
2.What is the daily frequency of encountering patients with ADR?		
One	29	26.4%
Two	13	11.8%
None	68	61.8%
3.Have you recorded the ADR you encountered on the patient's clinical record?		
Yes	77	70%
No	33	30%
4.Have you submitted any Adverse Drug Reaction (ADR) reports?		
Yes	29	26.4%
No	81	73.6%

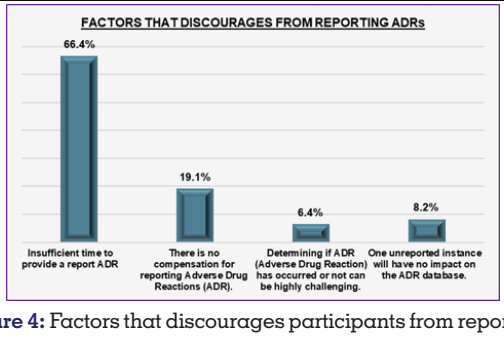

Figure 4: Factors that discourages participants from reporting Adverse Drug Reactions

Table 4: - Examining The Knowledge, Attitude, And Practice Of Interns & Postgraduates On The Scale Of Good, Fair, And Poor

Variables	Interns (n=73)						Postgraduates (n=37)						Chi-square value	p value
	Good		Fair		Poor		Good		Fair		Poor			
	n	%	n	%	n	%	n	%	n	%	n	%		
Knowledge	43	58.9%	20	27.4%	10	13.7%	20	54.1%	09	24.3%	08	21.6%	55.296	0.001*
Attitude	34	46.6%	22	30.1%	17	23.3%	14	37.8%	12	32.4%	11	29.7%	64.873	0.001*
Practice	20	27.4%	32	43.8%	21	28.8%	18	48.6%	10	27 %	09	24.3%	88.148	0.001*

DISCUSSION

According to the findings of this study, the knowledge and attitude of interns and post-graduates regarding adverse drug reaction (ADR) reporting were evaluated utilizing important aspects of pharmacovigilance. The results were found to be significant ($P < 0.001$*). The interns and postgraduates demonstrated a commendable level of expertise. Understanding interns' and postgraduates' proficiency in ADR reporting may be attributed to the integration of a pharmacovigilance program into the medical education curriculum, which has standardized our research findings. This remark aligns with a comparable study carried out by Schuttle T et al,[7] in Amsterdam, Netherlands. The study found that healthcare professionals had noteworthy enhancements in adverse drug reaction (ADR) reporting after the implementation of training programs focused on pharmacovigilance and ADR reporting, with statistical significance ($P < 0.05$*). Attitude was good in interns and postgraduates, similar results were observed in a cross-sectional study done by Upadhyaya et al,[8] where it was revealed that interns and postgraduates had a similar positive attitude viewpoint. They agreed that reporting adverse drug reactions (ADRs) leads to an increase in the quality of life. Furthermore, there was a strong consensus among them that ADR reporting should be required in every institution. The prevalence of intern participation in ADR reporting is lower compared to that of postgraduates. This phenomenon may be attributed to interns' apprehension towards extensive documentation, resulting in reduced reporting.

CONCLUSIONS

Based on this study, it can be inferred that both interns and postgraduates possess a solid understanding of ADR reporting. However, interns lack practical experience in their daily responsibilities owing to apprehension about extensive paperwork, while postgraduates lack the necessary commitment towards ADR reporting due to demanding schedules. The majority of the participants, namely interns and post-graduates, considered ADR reporting to be their main obligation, alongside ensuring patient safety. Providing regular training and raising awareness among future medical professionals regarding adverse drug reaction reporting can improve patient adherence and eliminate life-threatening consequences. They also recommend that institutions establish a distinct operational entity to gather ADR reports, considering their demanding work schedules.

REFERENCES

1. Pahuja R, Shrivastava B, Sharma PK, Kishore K, Mahajan S, Sood R. Awareness on adverse drug reaction reporting system in India: A consumer survey. Am J Phytomed Clin Ther. 2014;2:1361-9.
2. Ganesan S, Sandhiya S, Subrahmanyam DK. Frequency of ADRs and their economic impact in a tertiary care public sector hospital in South India. SBV J Basic Clin Appl Health Sci 2020;3:23-31.
3. Mwakawanga DL, Kilonzi M, Philipo EG, Martine A, Mbilinyi T, Kileo NF, Mkinga B, Shonyella CJ, Mohamedi JA, Clement A, Mwasomola D, Mushy SE, Sirili N. Pharmacovigilance and Adverse Drug Reactions Reporting: Healthcare Providers' Experiences from Southern Highland Tanzania. Adv Pharmacol Pharm Sci. 2023 Oct 16;2023:5537592.
4. D. Wolfe, F. Yazdi, S. Kanji et al., "Incidence, causes, and consequences of preventable adverse drug reactions occurring in inpatients: a systematic review of systematic reviews," PLoS. 2018;13(10).

5. R. K. Sahu, R. Yadav, P. Prasad, A. Roy, and S. Chandrakar, "Adverse drug reactions monitoring: prospects and impending challenges for pharmacovigilance," SpringerPlus. 2014;3(1):695.
6. W. Srisuriyachanchai, A. R. Cox, and N. Jarernsiripornkul, "Exploring healthcare professionals' practices and attitudes towards monitoring and reporting of severe adverse drug reactions," Healthcare. 2022;10(6):1077-2022.
7. Schutte T, Tichelaar J, Reumerman MO, van Eekeren R, Rissmann R, Kramers C, Richir MC, van Puijenbroek EP, van Agtmael MA; Education Committee/Working Group Research in Education of the Dutch Society of Clinical Pharmacology and Biopharmacy (NVKF&B), Utrecht, The Netherlands. Pharmacovigilance Skills, Knowledge and Attitudes in our Future Doctors - A Nationwide Study in the Netherlands. Basic Clin Pharmacol Toxicol. 2017;120(5):475-481.
8. Upadhyaya HB, Vora MB, Nagar JG, Patel PB. Knowledge, attitude and practices toward pharmacovigilance and adverse drug reactions in postgraduate students of Tertiary Care Hospital in Gujarat. J Adv Pharm Technol Res 2015;6:29-34.