ORIGINAL RESEARCH

Knowledge, Attitudes, and Practices of Adverse Drug Reactions among a Spectrum of Health Workers: A Pharmacovigilance Study from a Teaching Hospital in Eastern India

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Received on: 27 May 2024; *Accepted on:* 18 June 2024; *Published on:* 20 March 2025

Abstract

Introduction: This research paper examines the knowledge, attitudes, and practices (KAP) of adverse drug reactions (ADRs) among healthcare professionals in a teaching hospital in eastern India. The study aims to assess their understanding of ADR reporting and draw conclusions about their role in patient safety.

Materials and methods: A cross-sectional study was conducted with medical undergraduate students, medical postgraduates, medical interns, and nursing personnel. Participants completed a questionnaire consisting of knowledge, attitude, and practice-based questions. Data analysis was performed using statistical software.

Results: A total of 264 participants took part in the study. Medical undergraduates and postgraduates had higher knowledge scores compared to interns and nursing personnel. Attitudes towards ADR reporting were more positive among medical students and interns. Practice scores revealed a gap between identifying and reporting ADRs, with postgraduates exhibiting the highest reporting practices.

Conclusion: There are variations in the KAP of ADRs among healthcare professionals. Continuous education and training programs are needed to improve pharmacovigilance practices, particularly among nursing personnel. Integrating ADR reporting into curricula can enhance patient safety and promote rational medication use.

Keywords: Adverse drug reaction, Knowledge, attitudes, and practices, Medical students, Nursing students, Patient safety, Pharmacovigilance.

Bengal Physician Journal (2025): 10.5005/jp-journals-10070-8052

Introduction

According to the WHO, pharmacovigilance is "The pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long- and short-term side effects of medicines".[1] Ensuring that adverse drug reactions (ADRs) are reported accurately and promptly is essential for effective pharmacovigilance. A serious adverse event (SAE) is defined as any untoward medical occurrence at any dose that:

- Results in death.
- Is life-threatening.
- Requires inpatient hospitalization or causes prolongation of existing hospitalization.
- Results in persistent or significant disability/incapacity.
- May have caused a congenital anomaly/birth defect, or
- Requires intervention to prevent permanent impairment or damage.[2]

Studies have suggested that between 2.9 and 5.6% of hospital admissions are attributable to ADRs, and up to 35% of hospitalized patients may experience an ADR during their stay.[3] A suspected unexpected adverse reaction (SUSAR) is characterized as an adverse response to a study drug that is unintended, is not described in the relevant product information, and meets one of the criteria for seriousness. The spontaneous reporting of ADRs continues to be fundamental and a primary source of information for pharmacovigilance, playing a crucial role in ensuring patient safety. The Pharmacovigilance Programme of India (PvPI), which is overseen by the Central Drug Standard Control Organization (CDSCO), makes contributions to the international ADR reporting center on behalf of India.[4] The rates of reporting are grossly inadequate though due to many factors.[5–7] Numerous studies have demonstrated a lack of adequate knowledge and awareness among doctors regarding the reporting of ADRs. The knowledge and attitudes of doctors significantly impact the frequency of ADR reporting. Understanding the factors that influence ADR reporting is crucial for enabling the designing the remedial measures,[8] the orientation of undergraduate students, postgraduate students, medical interns, and nursing personnel toward ADR reporting is a poorly studied area in this respect even though they are capable of contributing such information at various levels in a teaching hospital. The existing literature is very scant in this regard and our study was designed to overcome this lacuna; more so because such data is sparsely

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How to cite this article: Maitra A, Asad M, Mondal S, *et al*. Knowledge, Attitudes, and Practices of Adverse Drug Reactions among a Spectrum of Health Workers: A Pharmacovigilance Study from a Teaching Hospital in Eastern India. Bengal Physician Journal 2025;12(1):29–33.

Source of support: Nil

Conflict of interest: None

reported by any private teaching institute from Eastern India. This study aimed to assess the knowledge, attitudes, and practices (KAP) related to ADRs among the participants and formulate significant conclusions about their role in pharmacovigilance practices.

Materials and Methods

This descriptive cross-sectional epidemiological study was performed in the pharmacology department along with various departments of KPC Medical College & Hospital, Jadavpur, West Bengal, India. Ethics clearance was obtained (KPCMCH/IEC/2022-23/08) from the Institutional Ethics Committee.

The medical undergraduate, medical postgraduate students, medical interns, and nursing personnel of KPC Medical College & Hospital were included in the study.

Procedure

All consenting participants were provided a pre-validated KAP questionnaire[9,10] about ADR reporting. The final questionnaire had 22 questions of which 13 were to assess knowledge, 6 and 3 were to assess attitude and practice, respectively. The knowledge question represented the burden of ADR, knowledge on reporting ADR, and pharmacovigilance. The attitude questions covered their perspectives on reporting ADRs, using a preformed scale that included options such as agree, disagree, and do not know. The practice questions gathered information on how they typically handled ADRs or adverse events in their clinical practice.

Inclusion Criteria and Exclusion Criteria

All consecutive subjects willing to participate after providing informed consent were recruited and those who were unwilling to give consent to participate or those who did not return the questionnaire within the stipulated time or those who did not complete all the items were excluded.

A total of 264 participants took part in the study, comprising 107 medical undergraduates, 37 medical postgraduates, 53 medical interns, and 67 nursing personnel.

Data Entry, Compilation, and Statistical Methods

Data was entered in MS Excel spreadsheet and analysis was done using Statistical Packages for Social Science (SPSS) (SPSS Inc, Chicago, IL, USA) version 26.0. Results were expressed as ratios and proportions. The Kruskal–Wallis test was applied for comparison among groups.

Results

A total of 264 students participated in this study, including 107 undergraduate medical students; 53 were rotatory medical interns; 37 were postgraduate medical students; and 67 were nursing students. The number of female participants was higher primarily due to the enrolment of female nursing students. The decadal breakup gave up a high number (246) of participants from the third decade whereas only a few (18) were above the age of 30. As far as experience was concerned, almost 75% of the respondents had less than 1 year of experience. There was a single participant who had an experience of more than 5 years. The demographic data is depicted in Table 1.

The responses to the 13 Knowledge-based; 6 attitude-based and 3 practice-based questions of this KAP study are summarized in Tables 2 to 4, respectively.

Table 1: Demographic details of the study participants

	Frequency (%)
Gender	
Male	112 (42.42)
Female	152 (57.58)
Age (Years)	
20–30	246 (93.18)
30–40	18 (6.82)
Professional status	
Medical undergraduates	107 (40.53)
Interns	53 (20.07)
Medical postgraduates	37 (14.01)
Nursing students	67 (25.38)
Experience (Year)	
<1	198 (75.00)
1–3	41 (15.53)
3–5	24 (9.09)
5–7	1 (0.38)

The knowledge domain questions revealed that 91.67% of undergraduate students, 86.36% of interns, 80% of postgraduate students, and only 43.33% of nursing students knew the correct definition of ADR. There was a significant difference in the perception of who can report an ADR between medical students/interns (>90%) and nursing students (56.67%). Overall knowledge about suspected adverse events and critical period to report SUSAR scored lowest.

The attitude domain answers revealed some interesting findings. About 84–88% of medical students/interns thought that ADR reporting should be voluntary as opposed to 71.67% of nursing students, and this difference in attitude was further exaggerated when they were asked whether it should be mandatory or not (~88–90% medical students/interns vs 51.67% nursing students). The nursing students were not sure of its essentiality. The majority of participants considered that ADR reporting should be financially rewarded.

There was gross mismatch between the practice of identifying an ADR (51% for undergraduates vs 76% for postgraduates) against the practice of actually reporting an ADR as per norms (7% for undergraduates vs 32% for postgraduates). Even amongst postgraduate students who could identify an ADR correctly (76%) the practice of reporting was less than desired (32%).

The means KAP score analysis vide (Table 5) turned up a few noticeable facts. The knowledge domain scores were best for postgraduate students (0.89) and least for nursing students (0.375). Attitude domain scores were almost the same in undergraduates/postgraduates and interns (0.88) but significantly less for nursing students (0.67) revealing the lack of sensitization about ADRs in the nursing curriculum. The difference between the mean score of knowledge and attitude domains was compared using the Kruskal–Wallis test and it was statistically significant amongst the subgroups. The difference in practice mean scores was compared using the Kruskal–Wallis test and it was not statistically significant.

The small number of participants had chosen more than one probable reason for underreporting (Table 6). The most common response was not bound to report ADRs (52.27%), the second and third most common reason for underreporting was the loss of patient confidentiality (48.86%) and not sure about the

Table 2: Response to knowledge-based questions

	Number (%) participants responded correctly			
	Medical undergraduates (n = 96)	*Interns (n = 44)*	*Medical postgraduates (n = 25)*	*Nurses (n = 60)*
What do you understand by pharmacovigilance?	87 (90.62)	37 (84.09)	22 (88.00)	26 (43.33)
The important purpose of pharmacovigilance is (Most appropriate one)?	87 (90.62)	36 (81.81)	22 (88.00)	29 (48.33)
Define ADR*	88 (91.67)	38 (86.36)	20 (80.00)	6 (43.33)
Are the entire ADRs* known before the drug is released into the market?	79 (82.29)	37 (84.09)	21 (84.00)	21 (35.00)
What type of ADR* is necessary to report?	86 (89.58)	39 (88.64)	22 (88.00)	23 (38.33)
What constitutes a serious adverse event?	83 (86.45)	39 (88.63)	23 (92.00)	25 (41.67)
Who gets the benefit of reporting an ADR*?	85 (88.54)	38 (86.36)	23 (92.00)	27 (45.00)
Should the reactions due to blood transfusion be reported?	85 (88.54)	35 (79.54)	21 (84.00)	26 (43.33)
Should the reactions due to vaccination be reported?	81 (84.37)	36 (81.81)	21 (84.00)	19 (31.67)
Who can report an ADR*?	89 (92.71)	41 (93.18)	23 (92.00)	34 (56.67)
To whom does an ADR* have to be reported?	90 (93.75)	40 (90.91)	24 (96.00)	17 (28.33)
Suspected serious ADR* reports should be sent to AMC† within how many days?	79 (82.29)	31 (70.45)	19 (76.00)	11 (18.33)
Does your hospital have an ADR* monitoring center?	84 (87.50)	39 (88.64)	22 (88.00)	17 (28.33)
Are you aware of any drug that has been banned in the world due to ADR*?	91 (94.79)	40 (90.91)	24 (96.00)	24 (40.00)

*ADR, adverse drug reaction; †AMC, adverse drug monitoring centre

Table 3: Response to attitude-based questions

	Number (%) participants responded YES as answer			
	Medical undergraduates (n = 96)	*Interns (n = 44)*	*Medical postgraduates (n = 25)*	*Nurses (n = 60)*
One should be certain of the ADR due to a particular drug	79 (82.29)	36 (81.82)	21 (84.00)	37 (61.67)
One should have a suspicion of possible ADR during treatment	85 (88.54)	38 (86.36)	22 (88.00)	39 (65.00)
ADR reporting by one person can make a significant difference to the community	84 (87.50)	39 (88.64)	22 (88.00)	41 (68.33)
ADR reporting in the hospital by healthcare professionals should be voluntary	85 (88.54)	37 (84.09)	21 (84.00)	43 (71.67)
ADR reporting in the hospital should be mandatory	87 (90.62)	40 (90.90)	22 (88.00)	31 (51.67)
ADR reporting in the hospital should be financially rewarded	91 (94.79)	41 (93.18)	23 (92.00)	45 (75.00)

Table 4: Response to practice-based questions

	Number (%) participants responded YES as answer			
	Medical undergraduates (n = 96)	*Interns (n = 44)*	*Medical postgraduates (n = 25)*	*Nurses (n = 60)*
Have you ever identified an ADR in any patient?	49 (51.04)	32 (72.72)	19 (76.00)	37 (61.67)
Have you ever reported an ADR?	7 (7.29)	7 (15.91)	8 (32.00)	11 (18.33)
I am following approaches in preventing ADR during my practice/prevented ADR during practice	27 (28.13)	21 (47.72)	19 (76.00)	29 (48.33)

causal relationship (46.97%). The reason with the least number of responses was lack of remuneration (14.02%).

Discussion

The present study was a questionnaire-based investigation conducted on MBBS second-phase students, postgraduate students, and nursing students in a tertiary care teaching hospital. Several studies have explored healthcare workers' understanding, attitudes, and practices in monitoring and reporting ADRs, but only a handful have focused on the post-COVID-19 era. The average knowledge score in the study by Desai et al.[9] conducted among doctors was 38.2%. In our study, there was a statistically

Table 5: Mean score comparison

Variables	*Medical undergraduates (n = 96)*	*Interns (n = 44)*	*Medical postgraduates (n = 25)*	*Nurses (n = 60)*	*p-value*	*KW*
Knowledge	0.85 ± 0.049	0.84 ± 0.153	0.89 ± 0.121	0.375 ± 0.196	0.000	33.271
Attitude	0.88 ± 0.03	0.86 ± 0.03	0.86 ± 0.03	0.67 ± 0.06	0.004	13.439
Practice	0.29 ± 0.17	0.45 ± 0.22	0.60 ± 0.19	0.42 ± 0.18	0.390	3.008

*KW, Kruskal–Wallis

Table 6: Reason for underreporting

	Reason for underreporting				
	Medical undergraduates n = 96 (expressed in %)	*Interns n = 44 (expressed in %)*	*Medical postgraduates n = 25 (expressed in %)*	*Nurses n = 60 (expressed in %)*	*Mean responses*
Do not know the procedure or whom to report	41 (42.71)	22 (50.00)	11 (44.00)	37 (61.67)	111 (42.05)
Not sure with the reaction and the drug	53 (55.21)	17 (38.63)	05 (20.00)	49 (81.67)	124 (46.97)
No need to report recognized reactions again	24 (25.00)	11 (25.00)	06 (24.00)	51 (85.00)	92 (34.84)
Not bound to report ADRS	66 (68.75)	19 (43.18)	04 (16.00)	49 (81.67)	138 (52.27)
No need to report as drugs come well-tested	23 (23.96)	12 (27.27)	04 (16.00)	47 (78.33)	86 (32.58)
Reporting reactions will not contribute to knowledge	48 (50.00)	23 (52.27)	05 (20.00)	31 (51.67)	107 (40.53)
Patient confidentiality may be lost	51 (53.12)	27 (61.36)	07 (28.00)	44 (73.33)	129 (48.86)
Procedure cumbersome/extra work	43 (44.79)	20 (45.45)	11 (44.00)	19 (31.67)	93 (35.28)
Lack of time	42 (43.75)	20 (45.45)	12 (48.00)	20 (33.33)	94 (35.61)
Fear of litigation from patient's side	44 (45.83)	21 (47.27)	12 (48.00)	35 (58.33)	112 (42.42)
Non-remuneration for reporting	14 (14.58)	09 (20.45)	03 (12.00)	11 (18.33)	37 (14.02)
Lack of confidence to discuss ADR with colleagues	39 (40.62)	20 (45.45)	10 (40.00)	23 (38.33)	92 (34.85)

significant difference in the mean scores of the knowledge domain among all groups ($p < 0.00$) with a stark difference in knowledge among medical and nursing personnel. This is consistent with the findings of Adiga and Banavalikar.[10] In comparison to the aforementioned study, our participants demonstrated significantly better knowledge about ADRs. One remarkable aspect was that knowledge scores dipped for interns as compared to undergraduate or postgraduate students which may reflect the attrition of knowledge from bench to bedside practice.

Regarding attitude scores, it was observed that all three groups of medical students had almost equal scores and furthermore, it was better than nursing staff scores, underscoring the point that this domain needs to be better addressed during nursing training. These findings align with the studies by Acharya et al. and Gupta et al.[11,12]

The practice score findings were notable by the reduction of scores as compared to knowledge or attitude scores in all four subgroups. This is demonstrably the outcome of poor orientation amongst these groups toward pharmacovigilance practices even though they were not lacking in knowledge. Numerous studies in India have reported the same observation.[2] The most common reason for underreporting ADRs was the misconception that the participants did not have the obligation to report (not bound to report ADRs is 52%). Lack of remuneration was the least of the concerns for all groups (14%). These findings are in line with South Asian studies by Mustafa et al. and Upadhyaya et al.[13,14] Few other issues like not knowing the procedure or whom to report (46%); loss of patient confidentiality (42%) and fear of litigation (42%) were substantial obstacles to the practice of ADR reporting.

A constant effort has been put into reinforcing spontaneous reporting and active surveillance practices to overcome the challenge of under-reporting. The main reasons for underreporting pointed out as lack of knowledge on how to report (28.2%), and lack of knowledge on reporting procedure (20%) in a study by Ray and Venugopal which is somewhat in alignment with our study where the lack of knowledge scored 42%.[3] Many study participants (47%) in this study were not sure if the reaction was due to the drug (causality) which is in agreement with the findings of the work by Mustafa et al. The major reasons for underreporting in this study were: the failure to address the fact of essentiality reporting ADR; the fear of loss of confidentiality of a patient and the fear of future litigation, which is different from other studies, which may be attributable to the naivety of the study population. Our participants are at the forefront of identifying, documenting, and advising patients about potential ADRs; but their ideas about the actual practice of reporting ADRs are fraught with various misconceptions. Proper sensitization and periodic campaigns for pharmacovigilance are absolute bedrocks of a robust foundation for pharmacovigilance. Thus, structured training and evaluation of the stakeholders of the pharmacovigilance program is essential to ensure patient safety.

The limitations of this study are that it includes only one center in West Bengal which does not represent the overall actual picture and so reduces generalizability. Convenience sampling is associated with selection bias. Cross-sectional design only captures momentary reflection. Consecutive recording of pre-tests, training, and post-tests could be a more scientific way of evaluation. This

study pointed toward the need for a continuous teaching and training program along with periodic practice evaluation. The cornerstone of a robust pharmacovigilance program requires 360-degree participation of all stakeholders. There is an opportunity to utilize the new competency-based undergraduate and postgraduate curricula for integrating ADR reporting practices.

Recommendation

The pharmacovigilance cell of all teaching institutes should include all the stakeholders at every tier to provide them with better and updated sensitization and keep them abreast with the statutory practices vis a vis current regulatory norms. These should have periodic evaluations for inherent checks and balances institutionally. The KAP model is an effective tool in this context.

Conclusion

This study has contributed to the understanding of pharmacovigilance practices and that they are not enough among undergraduate medical students, postgraduate medical students, and nursing staff in a teaching hospital. The results of this study can be utilized to formulate strategies aimed at enhancing the KAP of pharmacovigilance among healthcare professionals. This, in turn, will contribute to safeguarding patient safety and fostering the rational use of medications.

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Announcement

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Muscle-specific Tyrosine Kinase Antibody-positive Myasthenia Gravis Unmasked by Fluoroquinolone: A Case Report

Tino Baby, Syed Fahrudeen Munnaver PK, Sowmini Perumal R, Lakshmanan Sankaranarayanan, Malcolm Jeyaraj, Sakthi Velayutham, Kannan Vellaichamy, Viveka Saravanan, Mugundhan Krishnan. Bengal Physician Journal 2024;11(1):35–37. DOI: 10.5005/jp-journals-10070-8023