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Original Research Article

Evaluation of pharmacovigilance related knowledge, attitude and practice among healthcare professionals and students in a tertiary-care hospital: a cross-sectional study

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ABSTRACT

Background: Pharmacovigilance (PV) plays a critical role in ensuring medication safety by identifying, evaluating and preventing adverse drug reactions (ADRs). Assessing the knowledge, attitude and practice (KAP) of healthcare professionals is essential for strengthening ADR reporting systems. To assess the knowledge, attitude and practice (KAP) related to pharmacovigilance among healthcare professionals and students and to analyse the association of KAP scores with age and professional category.
Methods: This cross-sectional study utilized the ICMR pharmacovigilance KAP questionnaire to assess responses from 332 participants. Descriptive statistics were applied, Kruskal–Wallis's test for intergroup comparison and Spearman's correlation was used to evaluate associations between age and KAP scores. Data on professional experience were not available. A p value<0.05 was considered statistically significant.
Results: The mean (±SD) knowledge, attitude and practice scores were 4.57±1.30, 3.20±0.74 and 4.29±1.46, respectively. Knowledge (H=9.68, p=0.046) and practice (H=9.83, p=0.043) differed significantly across professions. Age showed a very weak, non-significant correlation with knowledge (ρ=0.103, p=0.060) and no correlation with attitude (ρ=0.013, p=0.809), but a weak significant correlation with practice (ρ=0.188, p=0.0006).
Conclusion: Participants demonstrated moderate knowledge and practice scores with overall positive attitudes. Knowledge and practice varied significantly across professions, while attitude did not. Age showed only weak associations with KAP domains. These findings indicate the need for profession-specific pharmacovigilance training, particularly to strengthen knowledge and practice among students and nursing staff.

Keywords: Adverse drug reactions, ADR reporting, Attitude and practice, Healthcare professionals, Knowledge, Pharmacovigilance

INTRODUCTION

According to WHO, Pharmacovigilance is defined as the science and activities relating to the identification, assessment, understanding and prevention of adverse effects or any other drug-related problems.[1] Adverse drug reactions (ADR) are among the top ten leading cause of death in the world and most of these are thought to be preventable under a functional pharmacovigilance system that is necessary. In India, the Pharmacovigilance Programme of India (PvPI) under the Central Drugs Standard Control Organisation has stepped up numerous times to strengthen ADR monitoring in the country and

promote its reporting, yet people under-report adverse drug reactions as a major issue in the country.[2] KAP studies are conducted to determine the knowledge and reporting practices of ADRs among healthcare providers and students and to identify gaps in knowledge or attitudes that impede active ADR surveillance.[3] This study was conducted to assess the knowledge, attitudes and practices of pharmacovigilance among healthcare providers and their association with demographic variables.

METHODS

A descriptive cross-sectional study was conducted during the period of January 2024 to June 2024 at Pondicherry Institute of Medical Sciences, a tertiary-care teaching hospital located in Pondicherry, India. Study utilised a validated Indian Council of Medical Research (ICMR) pharmacovigilance knowledge, attitude and practice (KAP) questionnaire. The study was approved by the Institutional Ethics Committee (Ref. No. 2020-01284). Participation was voluntary and written informed consent was obtained. Participants anonymity and confidentiality were maintained.

Inclusion criteria

The study population consisted of doctors, nurses and healthcare students present during the study period and were willing to participate were included in the inclusion criteria.

Exclusion criteria

Those who refused to participate or did not complete the questionnaires were excluded for data analysis.

The questionnaire consisted of 20 multiple-choice items distributed across three domains: knowledge (7 items), attitude (4 items) and practice (8 items) and one question was about reasons for not reporting ADR. Each correct or positive response was awarded one point. Total scores ranged from 0 to 7 for knowledge, 0 to 4 for attitude and 0 to 8 for practice.

Statistical analysis

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) software. Descriptive statistics were expressed as mean and standard deviation. Differences in KAP scores among professional categories were analysed using the Kruskal–Wallis's test, while the association between age and KAP scores were assessed using Spearman's rank correlation coefficient. P-value of less than 0.05 was considered statistically significant.

RESULTS

Among the 332 participants, 253 (76.2%) were nurses, 42 (12.65%) were doctors and 37 (11.4%) were students. The average age was 28.62±7.8 years, ranging from 21 to 70 years

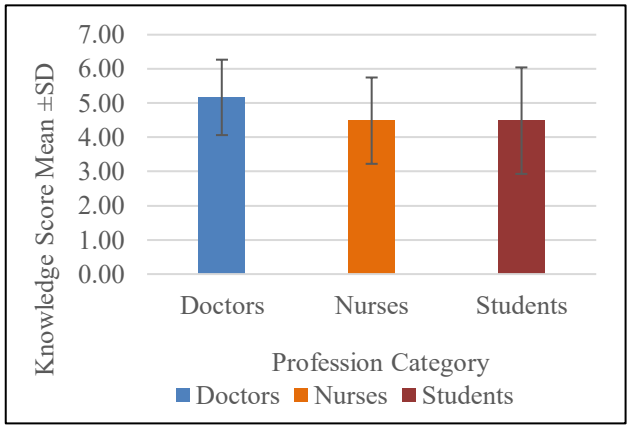

Figure 1: Knowledge score by profession.

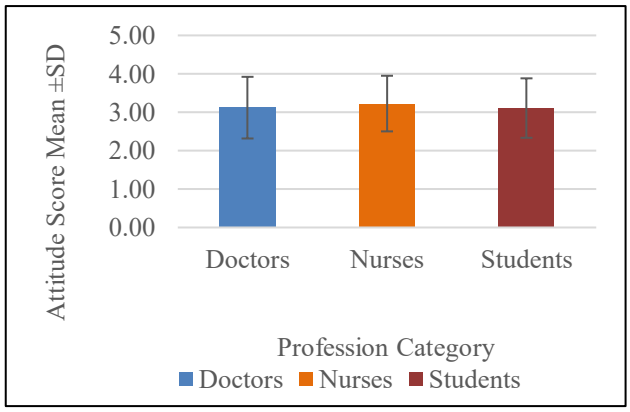

Figure 2: Attitude score by profession.

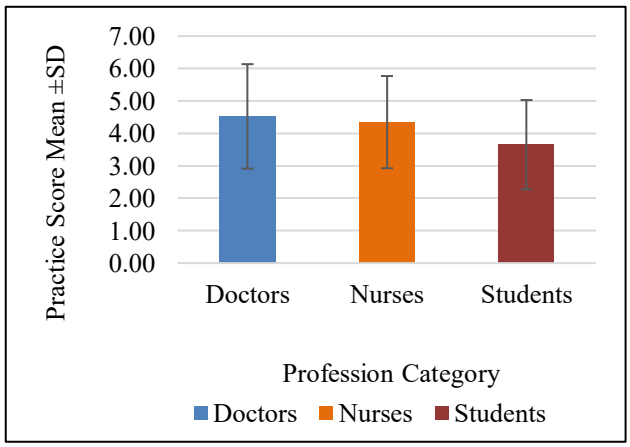

Figure 3: Practice score by profession.

The overall mean knowledge score was 4.57±1.29, indicating moderate awareness of pharmacovigilance concepts. The mean attitude score was 3.19±0.74, reflecting a generally positive attitude towards ADR reporting. The mean practice score was 4.29±1.47, suggesting suboptimal pharmacovigilance practices among participants. Doctors demonstrated higher mean

knowledge scores compared to nurses and students. Attitude scores were comparable across all professional groups. Practice scores were higher among doctors and nurses, while students showed relatively lower practice scores indicating lesser engagement in pharmacovigilance-related activities.

Responses to knowledge-related questions are presented in table 3. While a majority of participants correctly identified the definition of pharmacovigilance (69.9%) and were aware of the healthcare professionals responsible for ADR reporting (91.9%), only a small proportion correctly identified the primary purpose of pharmacovigilance (7.8%). Awareness regarding the national pharmacovigilance programme and the regulatory body responsible for ADR monitoring in India was moderate. Knowledge about the international ADR monitoring centre was comparatively lower.

Attitude-related responses are summarized in table 4. An overwhelmingly positive attitude towards pharmacovigilance was observed, with most participants agreeing that pharmacovigilance should be taught in detail (93.7%) and that ADR reporting is necessary (98.2%). However, fewer participants reported having read articles related to ADR prevention (44.6%), indicating gaps in proactive learning despite positive attitudes. table 5 presents responses related to pharmacovigilance practices. Although more than half of the participants had encountered ADRs in their professional practice (58.1%) and a majority had received training on ADR reporting (82.2%), only 36.7% had ever reported an ADR. Knowledge regarding timelines for reporting serious ADRs and identification of rare ADRs was limited, highlighting a gap between training and actual reporting practice.

Doctors showed higher knowledge scores compared to other groups with greater variability observed among students, while attitude scores were uniformly high across professions, indicating consistently positive perceptions towards pharmacovigilance. Practice scores were lower among students than among doctors and nurses suggesting limited involvement in ADR reporting activities. The correlation between age and KAP scores is shown in table 6. Age demonstrated a very weak positive correlation with knowledge scores and no correlation with attitude scores, both of which were statistically non-significant.

A weak but statistically significant positive correlation was observed between age and practice scores, indicating slightly better pharmacovigilance practices with increasing age. Intergroup comparison of KAP scores using the Kruskal–Wallis's test is presented in table 7. Significant differences were observed in knowledge and practice scores among professional groups. However, attitude scores did not differ significantly across professions, suggesting that positive attitudes towards pharmacovigilance were consistent regardless of professional background.

Table 1: Descriptive statistics of KAP scores.

Variable	Mean	SD	Range
Knowledge	4.57	1.29	0–7
Attitude	3.19	0.74	0–4
Practice	4.29	1.47	0–8

Table 2: Mean KAP scores by profession.

Profession	Knowledge (Mean±SD)	Attitude (Mean±SD)	Practice (Mean±SD)
Doctor	5.17±1.10	3.12±0.80	4.52±1.61
Nurse	4.49±1.26	3.23±0.72	4.35±1.42
Student	4.49±1.26	3.11±0.77	3.65±1.38

Table 3: Knowledge related questions and their responses.

Components of the questionnaire	Right response		Wrong response	
	N	(%)	N	(%)
Pharmacovigilance is defined as	232	69.9	100	30.1
The most important purpose of pharmacovigilance is	26	7.8	306	92.2
Do you think ADR reporting is professional obligation for you?	265	79.8	67	20.2
The healthcare professionals responsible for reporting ADRs in a hospital is/are	305	91.9	27	8.1
Do you know regarding the existence of a National Pharmacovigilance Programme in India?	258	77.7	74	22.3
In India which regulatory body is responsible for monitoring ADRs?	243	73.2	89	26.8
Where the international centre for adverse drug reaction monitoring is located?	189	56.9	143	43.1

Table 4: Attitude related questions and their responses.

Components of the questionnaire	Right responses		Wrong responses	
	N	(%)	N	(%)
Do you think pharmacovigilance should be taught in detail to healthcare professionals?	311	93.7	21	6.3
Do you think reporting of adverse drug reaction is necessary?	326	98.2	6	1.8
Have you anytime read any article on prevention of adverse drug reactions?	148	44.6	184	55.4
What is your opinion about establishing ADR monitoring centre in every hospital?	277	83.4	55	16.6

Table 5: Practice related questions and their responses.

Components of the questionnaire	Right responses		Other responses	
	N	(%)	N	(%)
Have you ever experienced adverse drug reactions in your patient during your professional practice?	193	58.1	139	41.9
Have you ever been trained on how to report ADR?	273	82.2	59	17.8
Have you ever seen the ADR reporting form?	248	74.7	84	25.3
Have you ever reported ADR to the Pharmacovigilance centre?	122	36.7	210	63.3
When you report a serious ADR to the regulatory body in India, it must be done in	30	9	302	91
Rare ADRs can be identified in the following phase of a clinical trial	99	29.8	233	70.2
Which of the following methods is commonly employed by the healthcare professional to monitor adverse drug reactions of new drugs once they are launched in the market?	171	51.5	161	48.5
Is there any Pharmacovigilance Committee in your institute?	289	87	43	13

Table 6: Correlation between age and KAP scores.

Variable pair	Spearman rho (ρ)	P value	Interpretation
Age vs knowledge	0.103	0.06	Very weak positive; not significant
Age vs attitude	0.013	0.809	No correlation; not significant
Age vs practice	0.188	0.0006	Weak positive; statistically significant

Table 7: Differences in KAP scores among professions.

KAP domain	H statistic	P value	Interpretation
Knowledge	9.68	0.046	Significant difference across professions
Attitude	5.85	0.211	Not significant
Practice	9.83	0.043	Significant difference across professions

DISCUSSION

This cross-sectional study assessed pharmacovigilance-related knowledge, attitude and practice among healthcare professionals and students and demonstrated moderate knowledge and practice with consistently positive attitudes, a pattern widely reported in recent pharmacovigilance KAP studies from India and other low- and middle-income countries.[4–7] The moderate knowledge scores observed in the present study are comparable to recent Indian studies showing adequate awareness of pharmacovigilance concepts but limited understanding of its regulatory objectives and operational aspects.[5,6,8] Although most participants correctly identified the definition of pharmacovigilance and acknowledged ADR reporting as a professional obligation, only a small proportion recognized its primary purpose, a finding consistent with recent studies from India and neighbouring countries.[6,9] Poor awareness regarding timelines for serious ADR reporting and international ADR monitoring centres has also been documented in studies from Ethiopia and other developing settings, indicating persistent gaps in applied pharmacovigilance knowledge.[10] Knowledge scores differed significantly across professional categories, with doctors scoring higher than nurses and students. Similar trends have been reported in recent Indian tertiary-care hospital studies, where doctors demonstrated better knowledge due to greater clinical exposure and formal pharmacology training.[5,8,11] Lower knowledge levels

among students observed in the present study are consistent with recent reports from Saudi Arabia and Malaysia, emphasizing inadequate early exposure to pharmacovigilance education.[12,13]

Attitude towards pharmacovigilance was uniformly positive across all professional groups, with most participants supporting ADR reporting and the establishment of ADR monitoring centres. Comparable positive attitudes have been reported in recent studies from India, China and Saudi Arabia.[4,7,12] However, fewer participants reported engaging in self-directed learning such as reading ADR-related literature, a finding also noted in recent studies, suggesting that positive attitudes do not necessarily translate into active professional engagement.[6,9]

Despite training exposure and frequent encounters with ADRs, actual ADR reporting practice remained suboptimal, with only a minority of participants having ever submitted an ADR report. This knowledge–practice gap has been consistently highlighted in recent Indian and international studies.[6,9,10] Barriers such as uncertainty about reporting procedures, time constraints, lack of confidence and absence of feedback mechanisms have been cited as key contributors to under-reporting.[4,9]

Students demonstrated significantly lower practice scores, likely due to limited clinical responsibility and fewer opportunities for reporting, a trend also observed in recent teaching-hospital-based studies.[11-13] Age showed only a weak association with practice and no significant correlation with knowledge or attitude, reinforcing evidence that experience alone does not ensure effective pharmacovigilance behaviour.[10,14]

Overall, these findings highlight the need for structured, profession-specific pharmacovigilance training, early curricular integration for students, simplified ADR reporting systems and regular institutional feedback to strengthen reporting practices and improve patient safety outcomes.[4,6,9]

Limitations

The cross-sectional design of the study limits causal interpretation between knowledge, attitude and practice. As the study was conducted at a single tertiary-care teaching hospital using self-reported data from the participants, the findings may be affected due to response bias and may not be generalisable to other healthcare settings. Moreover, institutional records were not used for ADR reporting. Despite of these limitations, the study offers valuable insights into current pharmacovigilance knowledge, attitudes and practices among healthcare professionals and students, while also underscores the important areas for targeted educational interventions.

CONCLUSION

Healthcare professionals and students demonstrated moderate knowledge and practice with positive attitudes towards pharmacovigilance. Significant variations across professional groups indicate gaps in preparedness, especially among nursing staff. Targeted, profession-specific training and streamlined ADR reporting mechanisms are essential to enhance pharmacovigilance performance and patient safety.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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