



Original Article

Assessment of Knowledge, Attitude, and Practice Regarding Pharmacovigilance Among Undergraduate Healthcare Professionals in a Tertiary Care Teaching Hospital: A Cross-Sectional Study

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ABSTRACT

Background and Objective: Undergraduate healthcare professionals require an adequate understanding of pharmacovigilance (PV), adverse drug reactions (ADRs), and the importance of timely reporting. This study assessed the knowledge, attitude, and practice (KAP) of PV and ADR reporting among second-year medical, second-year nursing, final-year medical, final-year dental, and final-year nursing students at a tertiary care teaching hospital.

Methods: A cross-sectional descriptive study was conducted among 398 undergraduate healthcare professionals across five academic groups. A structured 20-item self-administered questionnaire consisting of open-ended and closed-ended items was used to assess participants' KAP toward PV and ADR reporting.

Results: Of 398 undergraduate healthcare professionals from five groups, there were second-year medical (n=96), second-year nursing (n=91), final-year medical (n=90), final-year nursing students (n=60), and final-year dental students (n=61). Knowledge toward PV varied across the groups. Attitude toward PV was favourable across all groups. Although most final-year medical and final-year nursing students encountered ADR cases, their reporting practice remained low. KAP scores significantly differed across the groups ($p < 0.05$ for all). Knowledge ($p = 0.001$) and practice scores ($p = 0.009$) were significantly higher among male participants.

Conclusion: Undergraduate healthcare professionals in our tertiary care hospital demonstrated a positive attitude but had limited knowledge and poor practice toward ADR reporting. These findings support the need for structured PV training, especially for second-year nursing and final-year dental curricula, to better implement ADR reporting practices to enhance patient safety.

Keywords: Adverse drug reaction, awareness, knowledge, pharmacovigilance.

INTRODUCTION

Adverse drug reactions (ADRs) are defined as “any noxious or unintended effect produced by a drug at standard therapeutic doses”.⁽¹⁾ Rapid drug development, increased use of over-the-counter medicines, antibiotic resistance, and medication errors have contributed to a rising risk of ADRs.^(2, 3) ADRs can result in death, life-threatening complications, prolonged hospitalization, reduced quality of life, and increased healthcare costs.⁽¹⁾ Globally, about 2% of ADRs are reported, and ADRs remain among the 4th-6th leading causes of death in the United States.^(4, 5) Pharmacovigilance (PV) is defined as the science and activities related to the detection, assessment, understanding, and prevention of adverse reactions to medicines.⁽²⁾

Healthcare professionals who frequently encounter ADRs during clinical postings should have adequate knowledge of PV and ADR reporting.⁽⁶⁾ However, potential barriers such as lack of knowledge, heavy workloads, time constraints, and lack

of formal training are contributing to ADR underreporting.(6, 7) Assessing the knowledge, attitude, and practices (KAP) of healthcare professionals toward PV is essential for identifying educational gaps and developing targeted educational interventions.

Previous studies have shown that although healthcare professionals had adequate knowledge and positive attitude toward PV, their reporting practices remain poor.(8-10) Early implementation of PV training has been shown to improve ADR reporting rates.(11) In our institution, undergraduate healthcare students receive structured training beginning in the second year. Although several studies have assessed the KAP among healthcare professionals, there is a dearth of literature assessing KAP among undergraduate healthcare professionals, specifically second- and final-year medical, nursing, and dental students. The study thus aimed to assess the KAP of PV and ADR reporting among undergraduate medical, nursing, and dental students at a tertiary care teaching hospital.

METHOD

Study design and population

This descriptive cross-sectional study was conducted at SDM College of Medical Sciences and Hospital, a tertiary care hospital in Dharwad, for a period of six months. The study included second-year medical and nursing students, as well as final-year medical, dental, and nursing students. Healthcare professionals who refused to participate were excluded from the study. Before study initiation, we obtained clearance from the institutional ethics committee (SDMIEC/0219/2018) and informed consent from all participants.

Data collection

Data were collected using a 20-item self-administered questionnaire containing open-ended and closed-ended questions. The questionnaire was designed to collect demographic data and assess KAP related to PV. The knowledge section consisted of 12 questions, each question scored either 0 or 1. The attitude section consisted of 5 questions, with response options Yes, no, don't know, perhaps. The practice section consisted of 3 questions assessing participants' practical engagement with PV and ADR reporting.

Statistical analysis

Data were analyzed using SPSS version 21 (IBM Corp). Categorical variables are presented as frequency or numbers. Continuous variables are given as Mean $\pm$ SD. Normality was assessed using the Shapiro-Wilk test and Q-Q plot. Normally distributed variables were compared using the independent t-test; non-normally distributed variables were compared using the Mann-Whitney *U* test or Kruskal-Wallis test to compare KAP scores across groups. $p < 0.05$ was considered statistically significant.

RESULTS

Our study included 398 undergraduate healthcare professionals; most participants were predominantly male (72.6%) and aged 21-23 years (54.8%) (Table 1). Second- and final-year medical students and second-year nursing students constituted nearly two-thirds (69.6%) of participants (Table 1).

Table 1. Demographic data of the participants (N=398)

Variable	Number of participants (%)
Age (years)	
18 – 20	179 (45%)
21 – 23	218 (54.8%)
>23	1 (0.2%)
Gender	
Female	109 (27.4%)
Male	289 (72.6%)
Current academic position	
Second-year Medical	96 (24.1%)
Second-year Nursing	91 (22.9%)
Final-year Dental	61 (15.3%)
Final-year Medical	90 (22.6%)
Final-year Nursing	60 (15.1%)

Knowledge of PV varied significantly across the groups. Overall, final-year medical students showed better PV knowledge across all domains. Among final-year medical students, 93.3% correctly identified the definition of PV, 90% identified drug safety issues, 100% correctly expanded Pharmacovigilance Programme of India, 98.9% identified CDSCO as the regulatory body responsible for ADR monitoring, 82.2% identified Naranjo algorithm as the most used causality assessment scale, 83.3% identified Ghaziabad as the location of the National Pharmacovigilance Centre, and 85.6%

identified JIPMER Pondicherry as a regional PV centre. In contrast, knowledge was comparatively low for several domains among second-year nursing and final-year dental students (Table 2).

Table 2. Knowledge of healthcare professionals toward pharmacovigilance and adverse drug reactions

Variables	Second-year medical (n=96)	Second-year nursing (n=91)	Final-year Dental (n=61)	Final-year medical (n=90)	Final-year nursing (n=60)
Define pharmacovigilance?					
The science of monitoring ADR's happening in a hospital	1 (1%)	16 (17.6%)	6 (9.8%)	0	7 (11.7%)
The process of improving the safety of Drugs	1 (1%)	13 (14.3%)	4 (6.6%)	2 (2.2%)	3 (5%)
The detection, assessment, understanding & prevention of adverse effects	87 (90.6%)	48 (52.7%)	34 (55.7%)	84 (93.3%)	48 (80%)
The science of detecting the type & incidence of ADR after a drug is marketed	7 (7.3%)	14 (15.4%)	17 (27.9%)	4 (4.4%)	2 (3.3%)
The important purpose of pharmacovigilance is					
To identify the safety of drugs	73 (76%)	54 (59.3%)	39 (63.9%)	81 (90%)	48 (80%)
To calculate the incidence of ADR's	8 (8.3%)	17 (18.7%)	6 (9.8%)	5 (5.6%)	4 (6.7%)
To identify predisposing factors to ADR	7 (7.3%)	18 (19.8%)	1 (1.6%)	1 (1.1%)	6 (10%)
To identify unrecognized ADRs	8 (8.3%)	2 (2.2%)	15 (24.6%)	3 (3.3%)	2 (3.3%)
A serious adverse event in India should be reported to the regulatory body within					
One day	11 (11.5%)	38 (41.8%)	18 (29.5%)	4 (4.4%)	25 (41.7%)
Seven calendar days	23 (24%)	36 (39.6%)	28 (45.9%)	13 (14.4%)	8 (13.3%)
Fourteen calendar days	61 (63.5%)	12 (13.2%)	12 (19.7%)	70 (77.8%)	26 (43.3%)
Fifteen calendar days	1 (1%)	5 (5.5%)	3 (4.9%)	3 (3.3%)	1 (1.7%)
The international centre for adverse drug reaction monitoring is in?					
United States of America	29 (30.2%)	59 (64.8%)	31 (50.8%)	23 (25.6%)	22 (36.7%)
Australia	3 (3.1%)	7 (7.7%)	3 (4.9%)	2 (2.2%)	1 (1.7%)
France	8 (8.3%)	1 (1.1%)	4 (6.6%)	4 (4.4%)	3 (5%)
Sweden	56 (58.3%)	24 (26.4%)	23 (37.7%)	61 (67.8%)	34 (56.7%)
What does PvPI stand for?					
National Pharmacovigilance programme	1 (1%)	2 (2.2%)	0	0	0
Pharmaceutical program me of India	0	2 (2.2%)	1 (1.6%)	0	0
Pharmacovigilance Programme of India	95 (99%)	85 (93.4%)	60 (98.4%)	90 (100%)	60 (100%)
American Pharmaceutical Association	0	2 (2.2%)	0	0	0
In India, which regulatory body is responsible for monitoring of ADR's?					
Central Drugs Standard Control Organization	91 (94.8%)	57 (62.6%)	47 (77%)	89 (98.9%)	53 (88.3%)

Indian Institute of Sciences	0	6 (6.6%)	2 (3.3%)	0	1 (1.7%)
Pharmacy Council of India	1 (1%)	19 (20.9%)	8 (13.1%)	0	4 (6.7%)
Medical Council of India	4 (4.2%)	9 (9.9%)	4 (6.6%)	1 (1.1%)	2 (3.3%)
Which of the following scales is most used to establish the causality of an ADR?					
Hartwig scale	21 (21.9%)	27 (29.7%)	7 (11.5%)	5 (5.6%)	11 (18.3%)
Naranjo algorithm	59 (61.5%)	25 (27.5%)	23 (37.7%)	74 (82.2%)	30 (50%)
Schumock and Thornton scale	11 (11.5%)	21 (23.1%)	20 (32.8%)	5 (5.6%)	10 (16.7%)
Karch & Lasagna scale	5 (5.2%)	18 (19.8%)	11 (18%)	6 (6.7%)	9 (15%)
Where is the National Pharmacovigilance Centre in India located?					
Ghaziabad	56 (58.3%)	35 (38.5%)	17 (27.9%)	75 (83.3%)	37 (61.7%)
Mumbai	7 (7.3%)	1 (1.1%)	12 (19.7%)	1 (1.1%)	5 (8.3%)
New Delhi	21 (21.9%)	45 (49.5%)	28 (45.9%)	11 (12.2%)	14 (23.3%)
Kolkata	12 (12.5%)	10 (11%)	4 (6.6%)	3 (3.3%)	4 (6.7%)
One among these is a Regional pharmacovigilance centre.					
SDM medical college & hospital	17 (17.7%)	34 (37.4%)	26 (42.6%)	3 (3.3%)	12 (20%)
JIPMER, Pondicherry	67 (69.8%)	18 (19.8%)	18 (29.5%)	77 (85.6%)	38 (63.3%)
JSS Medical College & Hospital, Mysore	8 (8.3%)	27 (29.7%)	6 (9.8%)	7 (7.8%)	5 (8.3%)
CMC, Vellore	4 (4.2%)	12 (13.2%)	11 (18%)	3 (3.3%)	5 (8.3%)
Which one of the following is the 'WHO online database' for reporting ADRs?					
ADR advisory committee	20 (20.8%)	43 (47.3%)	19 (31.1%)	6 (6.7%)	13 (21.7%)
Medsafe	20 (20.8%)	22 (24.2%)	16 (26.2%)	10 (11.1%)	7 (11.7%)
Vigiflow	48 (50%)	23 (25.3%)	14 (23%)	66 (73.3%)	35 (58.3%)
Med watch	8 (8.3%)	3 (3.3%)	12 (19.7%)	8 (8.9%)	5 (8.3%)
Rare ADRs can be identified in the following phase of a clinical trial					
During phase-1 clinical trials	4 (4.2%)	28 (30.8%)	4 (6.6%)	7 (7.8%)	16 (26.7%)
During phase-2 clinical trials	18 (18.8%)	34 (37.4%)	20 (32.8%)	5 (5.6%)	4 (6.7%)
During phase-3 clinical trials	24 (25%)	21 (23.1%)	10 (16.4%)	9 (10%)	1 (1.7%)
During phase-4 clinical trials	50 (52.1%)	8 (8.8%)	27 (44.3%)	69 (76.7%)	39 (65%)
The healthcare professionals responsible for reporting ADR in a hospital is/are					
Doctor	19 (19.8%)	2 (2.2%)	18 (29.5%)	31 (34.4%)	5 (8.3%)
Pharmacist	8 (8.3%)	2 (2.2%)	6 (9.8%)	1 (1.1%)	2 (3.3%)
Nurses	5 (5.2%)	22 (24.2%)	4 (6.6%)	4 (4.4%)	9 (15%)
All of the above	64 (66.7%)	65 (71.4%)	33 (54.1%)	54 (60%)	44 (73.3%)

ADR, adverse drug reaction; PvPI, Pharmacovigilance Programme of India

Attitude toward PV and ADR reporting was positive across all groups. Most final-year medical students considered ADR reporting a professional obligation (92.2%) and supported establishing ADR monitoring centres (97.8%) in every hospital. Most final-year nursing students supported including ADR under pharmacology practical (90%), and nearly all final-year nursing students recognized the need for PV education to be taught in detail (98.3%) and considered ADR reporting necessary (100%) (Table 3).

Table 3. Attitude of healthcare professionals toward pharmacovigilance and adverse drug reactions

Variables	Second-year medical (n=96)	Second-year nursing (n=91)	Final-year Dental (n=61)	Final-year medical (n=90)	Final-year nursing (n=60)
Should ADR reporting be included under pharmacology practical?					

Yes	64 (66.7%)	70 (76.9%)	45 (73.8%)	79 (87.8%)	54 (90%)
No	7 (7.3%)	5 (5.5%)	7 (11.5%)	0	1 (1.7%)
Don't know	15 (15.6%)	9 (9.9%)	3 (4.9%)	2 (2.2%)	5 (8.3%)
Perhaps	10 (10.4%)	7 (7.7%)	6 (9.8%)	9 (10%)	0
Do you think reporting is a professional obligation for you?					
Yes	57 (59.4%)	44 (48.4%)	40 (65.6%)	83 (92.2%)	53 (88.3%)
No	19 (19.8%)	17 (18.7%)	12 (19.7%)	6 (6.7%)	4 (6.7%)
Don't know	11 (11.5%)	18 (19.8%)	6 (9.8%)	1 (1.1%)	3 (5%)
Perhaps	9 (9.4%)	12 (13.2%)	3 (4.9%)	0	0
What is your opinion about establishing ADR monitoring centre in every hospital?					
Should be in every hospital	71 (74%)	66 (72.5%)	44 (72.1%)	88 (97.8%)	58 (96.7%)
Not necessary in every hospital	7 (7.3%)	4 (4.4%)	7 (11.5%)	1 (1.1%)	0
One in a city is sufficient	7 (7.3%)	6 (6.6%)	6 (9.8%)	1 (1.1%)	0
Depends on the number of bed size in the hospitals	11 (11.5%)	15 (16.5%)	4 (6.6%)	0	2 (3.3%)
Do you think reporting of ADR is necessary?					
Yes	89 (92.7%)	89 (97.8%)	61 (100%)	88 (97.8%)	60 (100%)
No	7 (7.3%)	1 (1.1%)	0	1 (1.1%)	0
Don't know	0	1 (1.1%)	0	0	0
Perhaps	0	0	0	1 (1.1%)	0
Do you think pharmacovigilance should be taught in detail to healthcare professionals?					
Yes	88 (91.7%)	86 (94.5%)	58 (95.1%)	87 (96.7%)	59 (98.3%)
No	8 (8.3%)	5 (5.5%)	3 (4.9%)	3 (3.3%)	1 (1.7%)

ADR, adverse drug reaction

Most final-year medical (81.1%) and final-year nursing (83.3%) students had come across an ADR case during ward postings; however, fewer than half had participated in ADR reporting. Nearly all second-year medical students (99%) were aware of the CDSCO ADR reporting form (Table 4).

Table 4. Practice of healthcare professionals toward pharmacovigilance and adverse drug reactions

Variables	Second-year medical (n=96)	Second-year nursing (n=91)	Final-year Dental (n=61)	Final-year medical (n=90)	Final-year nursing (n=60)
Have you ever seen a case of ADR during your ward posting?					
Yes	13 (13.5%)	48 (52.7%)	10 (16.4%)	73 (81.1%)	50 (83.3%)
No	83 (86.5%)	43 (47.3%)	51 (83.6%)	17 (18.9%)	10 (16.7%)
Have you seen an adverse drug reporting form by CDSCO?					
Yes	95 (99%)	21 (23.1%)	9 (14.8%)	87 (96.7%)	41 (68.3%)
No	1 (1%)	70 (76.9%)	52 (85.2%)	3 (3.3%)	19 (31.7%)
Have you ever played any role in reporting ADR from your institution?					
Yes	6 (6.3%)	10 (11%)	2 (3.3%)	38 (42.2%)	19 (31.7%)
No	90 (93.8%)	81 (89%)	59 (96.7%)	52 (57.8%)	41 (68.3%)

ADR, adverse drug reaction; CDSCO, Central Drugs Standard Control Organisation

Male participants had significantly higher knowledge ($p=0.001$), practice ($p=0.009$), and overall KAP scores ($p=0.001$) than female participants. However, attitude scores did not differ significantly by sex ($p=0.418$) (Table 5).

Table 5. Distribution of subjects based on KAP score over gender

Variable	Female	Male	p-value
Knowledge score	7.28 ± 2.95	8.34 ± 2.84	0.001*
Attitude score	4.19 ± 0.91	4.2 ± 1.03	0.418

Practice score	1.3 ± 1	1.59 ± 0.93	0.009*
Total score	12.78 ± 3.89	14.13 ± 3.94	0.001*

Knowledge, attitude, practice, and overall KAP scores differed significantly across five groups (all $p < 0.05$) (Table 6).

Table 6. Distribution of subjects based on KAP score over current academic position

Variables	Second-year medical	Second-year nursing	Final-year Dental	Final-year medical	Final-year nursing	p-value
Knowledge score	8.42 ± 2.47	5.03 ± 1.81	5.72 ± 2	9.9 ± 2.24	8.43 ± 2.94	<0.001*
Attitude score	3.78 ± 1.13	3.9 ± 0.844	4.15 ± 0.833	4.64 ± 0.754	4.68 ± 0.537	<0.05*
Practice score	1.29 ± 0.541	0.95 ± 0.861	0.34 ± 0.655	2.23 ± 0.750	1.97 ± 0.92	<0.001*
Total score	13.49 ± 2.99	9.88 ± 2.28	10.21 ± 2.25	16.78 ± 3.08	15.08 ± 3.67	<0.001*

*Indicates statistical significance

DISCUSSION

Our study assessed the KAP toward PV and ADR among undergraduate medical, dental, and nursing students at a tertiary care hospital. Our findings demonstrated that knowledge of PV varied significantly across the groups. Final-year medical students had the highest knowledge scores, while second-year nursing and final-year dental students scored lowest. Although attitude toward PV and ADR reporting was positive across all groups, participation in ADR reporting was low, highlighting a knowledge-practice gap.

Consistent with our study findings, a study conducted in the Central Region of Malawi also reported positive attitudes but limited knowledge and poor practices toward ADR reporting among healthcare professionals.(12) Another study by Raikar et al., revealed that medical students at a Vijayapura tertiary care hospital had superior knowledge regarding ADRs while nursing students had greater awareness of pharmacovigilance centres and ADR monitoring centres in India.(13) In contrast, Paul et al., in a study from eastern India, found that although both medical and nursing students had adequate knowledge and attitude toward PV, there was a significant difference between the groups in the ADR reporting process.(14) Inadequate coverage of PV courses in the health curriculum, lack of training on ADR reporting, and not knowing where and how to report the ADRs could be the main reasons for low reporting practice scores.(9, 12) Educational interventions have been shown to improve knowledge and attitude scores.(12, 15)

Male participants in our study had higher knowledge and practice scores than female participants, while attitude scores did not differ significantly by sex. Tekel et al similarly found significantly higher knowledge scores among male students ($p = 0.001$). (16) In contrast, a study by Alshakka et al., conducted in Aden-Yemen revealed no significant gender difference among pharmacy, dental, and medical students.(17) Although age was not evaluated in the present study, Tekel et al. further reported significantly higher knowledge scores among students aged 23 years or older than among those younger than 23 years ($p = 0.004$). (16)

Total KAP scores were significantly higher among medical students than among nursing and dental students. Structured pharmacology training and earlier exposure to patients might have strengthened medical students' ability to assess ADRs. Nursing students frequently encounter ADRs during patient care and monitor both therapeutic and non-therapeutic drug effects; however, less structured training in PV may explain their intermediate scores.(18, 19) In contrast, the later onset of clinical exposure among dental students explains their lower KAP scores. Consistent with our findings, Mahesh et al. reported significantly higher knowledge ($p = 0.05$), attitude ($p = 0.104$), and practice ($p = 0.033$) scores among medical students than dental students, although attitude scores did not differ significantly between the groups.(20) In another study, nursing students had higher mean attitude scores than pharmacy and medical students ($p = 0.017$), whereas pharmacy students achieved higher practice scores ($p < 0.001$). (16)

Overall, the study demonstrates that both final-year medical and final-year nursing students, provided with adequate training during their undergraduate education, could successfully implement PV programs and improve ADR practices. In addition to training, establishing ADR monitoring centers, conducting regular workshops, and implementing periodic awareness programs within the undergraduate curriculum can further strengthen PV practices. Furthermore, providing special training for second-year nursing and final-year dental students may increase their KAP toward PV and ADR reporting.

The study has a few potential limitations that need to be acknowledged. The study was conducted in our institute at a single tertiary care teaching hospital involving only medical, dental, and nursing students, which may limit the generalizability of the findings to other undergraduate healthcare professionals or other regions. Because our study has a predominantly male population, it is difficult to analyze the influence of gender on the study results. Future multicenter studies involving students from other paramedical courses could widen the generalizability of the findings. Future studies should also investigate factors contributing to ADR underreporting to implement necessary interventions for improving PV knowledge and ADR reporting practices.

CONCLUSION

Undergraduate healthcare professionals at our tertiary care hospital demonstrated a positive attitude but had limited knowledge and poor practice toward ADR reporting. Knowledge and attitude toward PV and ADR reporting were higher among final-year medical and final-year nursing students compared to other academic groups. However, ADR reporting practices across all groups were comparatively low, particularly among final-year dental students. These findings support the need for structured PV training, especially for second-year nursing and final-year dental curricula, to better implement ADR reporting practices to enhance patient safety.

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