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Original Research Article

Assessment of Knowledge, Attitude and Practice of Pharmacovigilance among Health Care Students: A Questionnaire Based Cross Sectional Study

Amulya Rao B[1], Arulraja S[2], Thilip Kumar Gnanadurai[3], Meghana Mandala[4], Niharika Lingamaneni[5]

[1]2nd year MBBS student, Chalmeda AnandRao Institute of Medical Sciences, Bommakal, Telangana, India.

[2]Assistant Professor, Department of Pharmacology, Swamy Vivekanandha Medical College Hospital & Research Institute, Tiruchengode, Tamilnadu, India.

[3]Associate Professor, Department of Physiology, Chalmeda AnandRao Institute of Medical Sciences, Bommakal, Telangana, India.

[4]MBBS Internship, Chalmeda AnandRao Institute of Medical Sciences, Bommakal, Telangana, India

[5]MBBS Internship, Chalmeda AnandRao Institute of Medical Sciences, Bommakal, Telangana, India

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Corresponding Author: Dr. Thilip Kumar Gnanadurai

Conflict of interest: Nil

Abstract:

Background: Adverse drug reactions (ADRs) are known causes for increased mortality, and morbidity. The aim of this study is to assess the knowledge, attitude, and practice of pharmacovigilance among the second year Medical, Pharmacy, Dental and Nursing students.

Materials and methods: This is a cross sectional questionnaire based study and 345 Health Care students from various branches of second year students were selected non-randomly as the participants. This study was conducted at CAIMS, Bommakal, Karimnagar. Institutional ethical committee approval was obtained from the Institution prior to the study. Pre-design validated and self administered Knowledge, attitude, and practices (KAP) questionnaire on Pharmacovigilance was structured in Google form and the link was sent to the students. The response was analyzed by chi – square test and one way ANOVA by using the SPSS software Version -20.

Results: The distribution of knowledge about the pharmacovigilance in the MBBS students have more adequate knowledge 44 (24.6%) than other professional students and the dental students have poor knowledge 28 (34.1) than other professional students. The awareness of ADRs reporting was higher in MBBS students 168(93.9%) than other professional students. Over all practice of ADR among the professional student showed more negative response.

Conclusion: This study concluded that the continuous education and training about the PV and ADR reporting system is necessary for all healthcare students.

Keyword: Adverse Drug Reaction, Pharmacovigilance, KAP questionnaire.

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Introduction

In this world, the Medical advancements occur in a blink of an eye where each and every day a new drug is introduced into the market to treat the human diseases. A drug is capable of producing both desirable and undesirable effects. The undesirable effects may cause adverse drug reactions which may lead to life threatening situations, As these adverse drug reactions can lead to serious problems, they must be monitored time to time which is ensured by pharmacovigilance program. Pharmacovigilance has been defined by the WHO [2002] as the 'science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug related problems. Its main purpose is to reduce the risk of drug-related harm to the patient [1].

Adverse drug reactions (ADRs) are one of the recognised causes of morbidity and mortality and also increasing the economic burden to the general public. Administration of drug in large population may helps in manifestation of rare adverse effects (1:100,000) [2, 3]. About 2.4% to 6.5% were reported with adverse reactions in the total hospital admissions. In India, the incidence of ADRs is 6.7% [4].

Pharmacovigilance program (PP) is playing a major role in the findings of ADRs and prohibition of various drugs from the market. The under

reporting of ADRs is considered as the major problems in PP [5].

National Pharmacovigilance Program was initiated in India in the year 2004 to detect and simultaneously report about ADR to ensure the drug safety, [6]. India is an active participant in this program and its contribution to UMC(Uppsala Monitoring Centre) database has rise from 0.5% in 2012 to 2% in 2013 making it seventh largest contributor of UMC drug safety database [7]. Even though past researches have been well documented about the KAP of pharmacovigilance there exist a less awareness of these ADR's among the health care students

Hence, the objective of our study is to assess and compare the knowledge, attitude and practice among the second year Medical, dental, physiotherapy and Nursing students towards pharmacovigilance.

Materials and Methods:

This cross sectional questionnaire based study was conducted in department of physiology, Chalmeda AnandRao Institute of Medical Sciences at Bommakal, Karimnagar.
A non-randomized sampling technique was used in this survey study and it was carried out in second-year voluntary Health Care students like MBBS, Dental, Nursing, and Pharmacy. The institutional ethical committee approved this study with an allotted number [IEC. CAIMS /2023/015]. As with participant's consent 345 Health care students were recruited in this study. Willing and 2nd year health care students from various branches were included in this study. Non-willing participants, non-health Care students and participants not return the questionnaire at a specific time was excluded from the study.

Study Procedure:

A clear instruction was given to all the participants about the study. Pre-design validated and self-administered KAP questionnaire on Pharmacovigilance was designed by the faculty of department of Pharmacology based on previous study. A validated KAP questionnaire (23) on pharmacovigilance was structured in Google form and the link was sent to the students. A set of 12 Knowledge questions were assessed the understanding about the pharmacovigilance and burden of ADR. The awareness question (7) contains the opinion, agreement about the ADR reporting. The practice questions contained the information about visit, initiate and training of participants regarding ADR. This study was conducted for three months duration to get the response from the participants and feeding the data in the excel sheet and analyze the data.

Statistical Analysis:

The collected data was entered in the excel sheet and the quantitative and qualitative data was analyzed by SPSS software 20 version. Quality data was analysed by chi square test and the quantitative data was denoted as mean ± SD and the significance was assessed by one way ANOVA.

Results

Table 1: Distribution of Knowledge composite score based on IQR in this study

Knowledge composite score Ranges	Distribution
0-5	Poor Knowledge
6-9	Moderate Knowledge
10-12	Adequate Knowledge

IQR = Inter Quartile Range

Table 1 showed that the Knowledge composite score was categorized as poor (0-5), moderate (6-9) and adequate knowledge (10-12) based on the percentile 25 and 75 from the acquired data

Table 2: Comparison of Knowledge composite score between different health care students by chi square test

Knowledge distribution	Health Care Students				Total N (%)
	MBBS N (%)	Dental N (%)	Nursing N (%)	Pharmacy N (%)	
Poor Knowledge	21 (11.7)	28 (34.1)	30 (36.1)	20 (44.5)	**99 (25.4)**
Moderate Knowledge	114 (63.7)	48 (58.5)	37 (44.6)	22 (48.9)	**221 (56.8)**
Adequate Knowledge	44 (24.6)	06 (7.3)	16 (19.3)	3 (06.7)	**69 (17.7)**
Total	**179 (100)**	**82 (100)**	**83 (100)**	**45 (100)**	**389 (100)**
X^2 Value =42.96, p value = 0.000* **					

p<0.05- ***p<0.001- statistically significant, ns- not significant

Table 2 showed that the distribution of knowledge about the pharmacovigilance in the MBBS students have more adequate knowledge 44 (24.6%) than other professional students and the dental students have poor knowledge 28 (34.1) than other professional students.

Table 3: Comparison of Knowledge composite score mean between different health care students by One way ANOVA

Parameter	Health Care Students				F value	p - value
	MBBS Mean ± SD. N =179	Dental Mean ± SD. N = 82	Nursing Mean ± SD. N = 83	Pharmacy Mean ± SD. N =45		
Knowledge composite score	8.07 ± 2.02	6.36 ± 2.33	6.83 ± 2.39	5.88 ± 2.27	19.48	**0.000*** **
Post Hoc Tukey Test (Inter group comparison)	MBBS – Dental: **0.000*** ** Dental – Nursing: 0.547 (ns) MBBS – Nursing: **0.000*** ** Dental – Pharmacy: 0.627 (ns) MBBS – Pharmacy: **0.000*** ** Nursing- Pharmacy: 0.096 (ns)					

p<0.05- ***p<0.001- statistically significant, ns- not significant

Table 3 showed that the knowledge composite score between the health care students. The composite score of MBBS students was 8.07 which were higher among the other branch students and the pharmacy students have less composite score than others. The intergroup comparison showed the significance among the MBBS and other professional students whereas no significant association between the dental, pharmacy and nursing students.

Table 4: Comparison of Awareness between different health care students by chi square test

Awareness Question	MBBS N =179		Dental N = 82		Nursing N = 83		Pharmacy N = 45		Total N (%) N =390 /p –value
	Yes N (%)	No N (%)	Yes N (%)	No N (%)	Yes N (%)	No N (%)	Yes N (%)	No N (%)	
AQ1	168(93.9)	11(6.1)	63 (76.8)	19(23.2)	72 (86.7)	11(13.3)	35 (77.8)	10(19.6)	**Y-338(86.9) N- 51 (13.1) P :0.001*** **
AQ2	165(92.2)	14 (7.8)	58(70.7)	24(29.3)	72 (86.7)	11(13.3)	34(75.6)	11(24.4)	**Y-329(84.6) N- 60 (15.4) P :0.000*** **
AQ3	150(83.8)	29 (16.2)	58(70.7)	24(29.3)	51(61.4)	32(38.6)	30(66.7)	15(33.3)	**Y-289(74.3) N- 100(25.7) P :0.001*** **
AQ4	150(83.8)	29 (16.2)	42(51.2)	40(41.7)	57 (68.7)	26(31.3)	30(66.7)	15(33.3)	**Y-279(71.7) N- 110(28.3) P:0.000*** **
AQ6	159(88.8)	20 (11.2)	43(52.4)	39(47.6)	70(84.3)	13(15.7)	26(67.8)	19(42.2)	**Y-298(76.6) N- 91 (23.4) P:0.000*** **

p<0.05-***p<0.001- statistically significant, ns- not significant

AQ1. One should be aware of the ADR of a particular drug? , AQ2. One should have a suspicion of possible ADR during treatment, AQ3. ADR reporting by one person can make a significant difference to the community, AQ4. ADR reporting in the hospital should be mandatory, AQ6. ADR reporting in hospital is required?

The awareness of ADRs reporting was higher in MBBS students than other professional students shown in table 4.

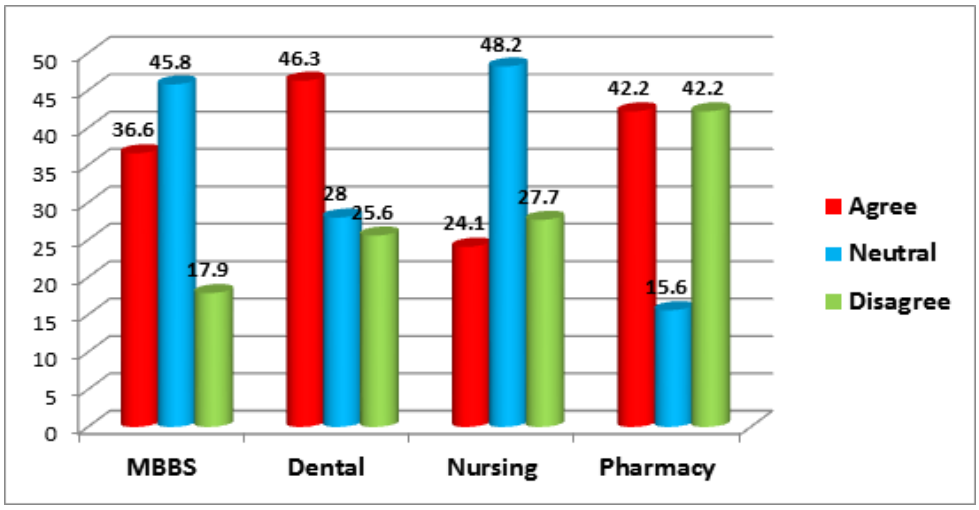

Figure 1: AQ5. ADR reporting in the hospital should be financially rewarded

Figure 1 showed that the likert type questionnaires for ADR reporting and financial rewarded. 46.3% of dental students agreed for this condition which was higher than the other branch students and 27.7% of nursing student were disagree which was more than the other professional students for this condition

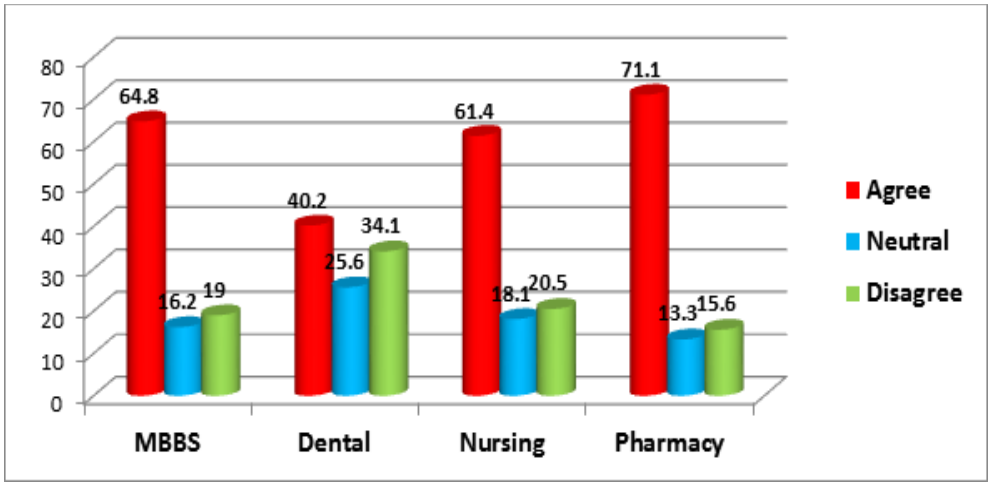

Figure 2: AQ7. ADR reporting in the hospital by healthcare professional should be voluntary?

Figure 2 showed that the likert type questionnaires for ADR reporting are voluntary by health care professional. 71.1 % of pharmacyl students agreed for this condition which was higher than the other branch students and 34.1 % of dental student were disagree which was more than the other professional students for this condition

Table 5: Comparison of practice between different health care students by chi square test

Practice Question		MBBS N =179 N (%)	Dental N = 82 N (%)	Nursing N = 83 N (%)	Pharmacy N = 45 N (%)	Total N= 345 N (%)	p - va1ue
PQ1	Yes	105(58.7)	38 (46.3)	56(67.5)	22 (48.9)	221 (56.8)	.031**
	No	74 (41.3)	44 (53.7)	27 (32.5)	23 (51.1)	168 (43.2)	
PQ2	Yes	67 (37.4)	32 (39)	34 (41)	16 (35.6)	149 (38.3)	0.926 (ns)
	No	112 (62.6)	50 (61)	49 (59)	29 (64.4)	240 (61.7)	
PQ3	Yes	112 (62.6)	31 (37.8)	49 (59)	31 (68.9)	206 (53)	0.000***
	No	67 (37.4)	51 (62.2)	34 (41)	14 (31.3)	183 (47)	
PQ4	Yes	64 (35.8)	68 (82.9)	40 (48.2)	22 (48.9)	140 (36)	0.000***
	No	115 (64.2)	14 (17.1)	43 (51.8)	23 (51.1)	249 (64)	

p<0.05- ***p<0.001- statistically significant, ns- not significant

PQ1. Have you ever seen the ADR reporting form? PQ2. Have you ever visited pharmacovigilance centre in your institution, PQ3. Have you ever been trained on how to report ADR? PQ4. Did you ever initiate to create awareness regarding pharmacovigilance.

Table 5 showed that the practice about ADR. Nearly more than half of the participants from all the branch never seen the ADR form and never visited the centre. Dental students less trained about ADR and most of the MBBS students not initiating the awareness regarding pharmacovigilance when compared to the other branch students. Over all the practice among the professional student showed more negative response.

Discussion

The present study was done to assess and compare the knowledge, attitude and practice of pharmacovigilance(PV) among the second year professional students of medical, dental, nursing and pharmacy students where these students may receive training and education about PV and ADRs.

The Knowledge composite score was categorized as poor (0-5), moderate [6-9] and adequate knowledge (10-12) based on the percentile 25 and 75 from the acquired data. In our study, we found that medical students have higher Knowledge regarding pharmacovigilance and ADR reporting in comparison to other Dentistry, Nursing and Pharmacy students. The awareness of ADRs reporting was higher in MBBS students than other professional. Regarding the practice, nearly more than half of the participants from all the branch never seen the ADR form and never visited the centre. Dental students less trained about ADR and most of the MBBS students not initiating the awareness regarding pharmacovigilance when compared to the other branch students. Over all the practice among the professional student showed more negative response.

MoniraAlwhaibi et al [8] found that the Pharmacy students have better knowledge, attitude and perceptions regarding pharmacovigilance and ADR reporting in comparison to medical, dentistry and nursing students.

Sivadasan S et al found that the pharmacy students have better knowledge, awareness and understanding about the PV and ADR reporting compared to medical students. Umair Khan M et al [9] conducted a study among final-year pharmacy and medical students in Pakistan and compared PV knowledge and reported that pharmacy students exhibited more knowledge and positive attitudes regarding their ability to handle and report ADRs than medical students. [10]

Rehan HS et al [11] reported that theKAP about ADR monitoring was low and the knowledge scores needed an improvement hence update of KAP about ADR and pharmacovigilance is necessary among the health care professionals. Graille V et al [12] conducted a survey among medical residents in France and reported that the majority have less knowledge about pharmacovigilance. Cosentino M et al [13] et al conducted a study in Italy and reported that doctors have less knowledge about ADRs and ADR reporting systems.

In our study, we found that the dental students have less knowledge about the pharmacovigilance. The findings from our study will suggest the use of interventions in the improvement of KAP about the healthcare professional students.

Conclusion:

We concluded from this study, the medical students have better attitude, knowledge towards ADRs and pharmacovigilance but regarding the practice related to pharmacovigilance found negative response among the second years health care students. Hence, we suggest that there is a need of continuous education and training about the pharmacovigilance and ADR reporting system for all healthcare students.

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