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Research Article

TO ASSESS THE KNOWLEDGE, ATTITUDE, AND PRACTICE OF PHARMACOVIGILANCE AND ADVERSE DRUG REACTION REPORTING AMONG THE UNDERGRADUATE AND POSTGRADUATE MEDICAL STUDENTS IN A TERTIARY CARE TEACHING HOSPITAL IN ASSAM: A QUESTIONNAIRE-BASED STUDY

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ABSTRACT

Objectives: Adverse drug reaction (ADR) is an important factor contributing to mortality and morbidity worldwide. Since undergraduate (UG) and postgraduate (PG) students are the future caregivers to the patients, they should have sound knowledge, a positive attitude, and good practice of Pharmacovigilance (PV). Hence this study was conducted to assess their knowledge, attitude, and practice (KAP) of PV and ADR reporting. Furthermore, secondarily this study tried to look into the impact of competency-based medical education (CBME) on the KAP of the students.

Methods: Questionnaire-based, observational, and cross-sectional study. The questionnaire was pre-validated and consisted of 30 questions to assess the KAP of UG and PG medical students of a tertiary care teaching hospital in Assam.

Results: A total of 419 students participated in the study. Data were analyzed using Microsoft Excel Sheet and the Student's *t*-test. Both UGs and PGs have good knowledge about PV, ADR, and the types of ADRs to be reported. They also have a positive attitude but in practice, only a few have filled up the ADR form. Mean score analysis showed p-value was significant for attitude and practice among the UGs and PGs and highly significant for KAP when the CBME and Old Curriculum were compared.

Conclusion: Although students have good knowledge and attitude, they need to improve in their practice. Regular training and awareness programs might help in educating them about PV and ADR reporting. However, the introduction of the CBME curriculum has been shown to improve the knowledge and attitude of the students about PV and ADR reporting.

Keywords: Pharmacovigilance, Adverse drug reactions reporting, Knowledge, attitude, and practice, Undergraduate, Postgraduate, Competency-based medical education.

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INTRODUCTION

Virtually a drug can affect every body system and result in the occurrence of adverse drug reactions (ADRs) [1]. The definition of ADR has been given by the World Health Organization (WHO) as "a drug response that is noxious and unintended, and that occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or the modification of physiological function" [2]. It is considered an important public health problem in terms of mortality, morbidity, and costs [3,4]. The information which is collected during the pre-marketing phase of drug development is incomplete regarding possible ADRs [5]. Most of the data regarding the safety of medicines are known once the products are in the market. Therefore, it is critically important to continuously monitor the safety of medicines in real-world settings, when they are used in conjunction with other products, among different patient populations, and patients with multiple illnesses. The WHO supports countries in implementing best pharmacovigilance (PV) practices, and communicates regulatory decisions and safety signals for medicinal products at a global level [6]. PV has been defined by the WHO as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine-related problem" [7]. The Government of India initiated the PV Program of India in July 2010 [8].

Spontaneous reporting of suspected ADRs by health-care professionals (HCPs) and pharmaceutical companies is the keystone of the National PV system and it is considered one of the best methods for the generation of signals about unexpected and uncommon ADRs [9,10].

Since medical students are the future caregivers to the patients, they must have sufficient knowledge and attitude about PV and ADR reporting and implement the same in their future practice to ensure rational and safe use of medicines, thereby reducing drug-related morbidity and mortality. With the introduction of the new competency-based medical education (CBME), it is expected that students are given better exposure to this topic than earlier.

Hence, this study was carried out to assess the knowledge, attitude, and practice (KAP) of PV and ADR Reporting among undergraduate (UG) and postgraduate (PG) medical students in a tertiary care teaching hospital in Assam. The study also attempted to study the impact of the CBME curriculum on the KAP of PV and ADR reporting.

METHODS

An observational, questionnaire-based, and cross-sectional study was carried out in a tertiary care teaching hospital in Assam. Before conducting our study, permission from the Institutional Ethics Committee was taken. Informed consent was also taken. The inclusion criteria were all 2nd professional and 3rd professional UG students, interns, and PG students who were willing to participate in the study and give informed consent. Informed consent was considered as the willingness to fill up the form. The exclusion criteria were students not willing to participate and not willing to give informed consent. The study was designed to be conducted over 2 months.

A questionnaire was prepared which included 30 questions, 10 each for assessing the KAP of PV and ADR reporting. It was prepared by modifying the questions included in the previously done similar studies [2,11-16]. Before delivering the forms to the participants, a pilot study was done to validate the questionnaire. Based on the pilot study,

the questions were a bit modified. It was then converted into Google form format and was shared with all the participants.

Each correct answer and each positive response was given a score of 1 whereas the negative response or wrong response was given a score of 0. The responses were collected and the data was transferred to Microsoft Excel 2010 and descriptive statistics such as mean, frequency, and percentage were calculated. Student's *t*-test was done to find the statistical difference between different groups. $p<0.05$ was considered significant and <0.01 highly significant. The data were presented as tables.

RESULTS

A total of 419 students participated in the study, out of which, 336 (80.19%) were UGs, and 83 PGs (19.81%). 257 students (61.34%) were under CBME and 162 students (38.66%) were under the Old curriculum (Table 1). Among the UGs, 212 (50.6%), 45 (10.74%),

Table 1: Sociodemographic characteristics of the study participants (n=419)

Variables	Category	Frequency (%)
Gender	Male	250 (59.67)
	Female	169 (40.33)
Age group (years)	Up to 20	48 (11.46)
	21–30	357 (85.20)
	31–40	13 (3.10)
	41–50	1 (0.24)
Professional qualification		
Undergraduate=336	2nd-year MBBS students	212 (50.60)
	3rd-year MBBS students	45 (10.74)
	4th-year MBBS students	68 (16.23)
	Intern	11 (2.62)
Postgraduate=83	Postgraduate medical students	83 (19.81)
Curriculum	CBME (2nd-year MBBS students+3rd-year MBBS students)	257 (61.34)
	Old curriculum (4th-year MBBS students+intern+postgraduate medical students)	162 (38.66)

CBME: Competency-based medical education

Table 2: Response about knowledge of UG and PG students, competency-based medical education and old curriculum students

S. No.	Question	Frequency				
		Overall (n=419), n (%)	Professional qualification		Curriculum	
			Undergraduate, n (%)	Postgraduate, n (%)	CBME, n (%)	Traditional, n (%)
1	What do you understand by pharmacovigilance?					
	a. Correct response	348 (83.05)	290 (86.31)	58 (69.88)	224 (87.16)	124 (76.54)
	b. Incorrect response	71 (16.95)	46 (13.69)	25 (30.12)	33 (12.84)	38 (23.46)
2	Why is pharmacovigilance needed?					
	a. Correct response	361 (86.16)	291 (86.61)	70 (84.34)	224 (87.16)	137 (84.57)
	b. Incorrect response	58 (13.84)	45 (13.39)	13 (15.66)	33 (12.84)	25 (15.43)
3	What do you understand by ADR?					
	a. Correct response	351 (83.77)	281 (83.63)	70 (84.34)	218 (84.82)	133 (82.10)
	b. Incorrect response	62 (14.80)	49 (14.58)	13 (15.66)	35 (13.62)	27 (16.67)
	c. Do not know	6 (1.43)	6 (1.79)	Nil	4 (1.56)	2 (1.23)
4	Who are the people that can report ADR?					
	a. Correct response	337 (80.43)	264 (78.57)	73 (87.95)	200 (77.82)	137 (84.57)
	b. Incorrect response	82 (19.57)	72 (21.43)	10 (12.05)	57 (22.18)	25 (15.43)
5	Have you seen an ADR reporting form?					
	a. Yes	239 (57.04)	212 (63.1)	27 (32.53)	203 (78.99)	36 (22.22)
	b. No	180 (42.96)	124 (36.9)	56 (67.47)	54 (21.01)	126 (77.78)
6	Is there a pharmacovigilance centre in your institution?					
	a. Yes	369 (88.07)	304 (90.48)	65 (78.31)	239 (93)	130 (80.25)
	b. No	50 (11.93)	32 (9.52)	18 (21.69)	18 (7)	32 (19.75)
7	Which of the following is a regional pharmacovigilance centre in North-East India?					
	a. Correct	312 (74.46)	265 (78.87)	47 (56.63)	206 (80.16)	106 (65.43)
	b. Incorrect	107 (25.54)	71 (21.13)	36 (43.37)	51 (19.84)	56 (34.57)
8	What are the types of ADR that have to be reported?					
	a. Correct	349 (83.29)	276 (82.14)	73 (87. 95)	211 (82.10)	138 (85.19)
	b. Incorrect	70 (16.71)	60 (17.86)	10 (12.05)	46 (17.90)	24 (14. 81)
9	ADRs can be reported for which of the following medicines?					
	a. Correct	352 (84.01)	278 (82.74)	74 (89.16)	212 (82.49)	140 (86.42)
	b. Incorrect	67 (15.99)	58 (17.26)	9 (10.84)	45 (17.51)	22 (13.58)
10	Are you aware of any drug banned due to ADR?					
	a. Correct	173 (41.29)	121 (36.01)	52 (62.65)	88 (34.24)	85 (52.47)
	b. Incorrect	246 (58.71)	215 (63.99)	31 (37.35)	169 (65.76)	77 (47.53)
	If yes, please specify		Students responded-139, correct answer-59			

ADR: Adverse drug reaction

68 (16.23%), and 11 (2.62%) were 2nd-year students, 3rd-year students, 4th-year students, and interns, respectively.

Knowledge-based questions

Table 2 shows the knowledge-based questions and their responses. It shows that 86.31% of UGs and 69.88% of PGs gave correct responses regarding the definition of PV while 83.63% of UGs and 84.34% of PGs gave correct responses regarding the definition of ADR. It was further seen that 87.16% of CBME students and 76.54% of Old Curriculum students gave correct responses about PV while 84.82% of CBME students and 82.1% of Old Curriculum students gave correct responses about ADR. 86.61% of UGs and 84.34% of PGs were aware that the most important purpose of PV is to identify the safety of the drug; 82.14% of UGs and 87.95% of PGs know the type of ADR to be reported; 82.74% of UGs and 89.16% of PGs were aware of types of medicines for which ADR can be reported.

Attitude-based questions

Table 3 shows attitude-based questions and their responses. A total of 99.05% think that PV should be taught to all health-care providers in detail. 99.28% agreed that reporting ADR is necessary. 93.08% of students think that all health-care providers should consider themselves professionally obliged to report ADRs. The majority of participants (99.76%) considered timely monitoring and reporting of

Table 3: Comparison of the attitude of undergraduate and postgraduate students, competency-based medical education and traditional curriculum

S. No.	Question	Frequency				
		Overall (n=419), n (%)	Professional qualification		Curriculum	
			Undergraduate, n (%)	Postgraduate, n (%)	CBME, n (%)	Traditional, n (%)
1	Do you think Pharmacovigilance should be taught to all healthcare providers in detail?					
	a. Yes	415 (99.05)	334 (99.40)	81 (97.59)	257 (100)	158 (97.53)
	b. No	4 (0.95)	2 (0.6)	2 (2.41)	0	4 (2.47)
2	Do you think the topic of Pharmacovigilance covered in your curriculum is sufficient for reporting ADR in your future practice?					
	a. Yes	235 (56.09)	210 (62.5)	25 (30.12)	185 (71.98)	50 (30.86)
	b. No	184 (43.91)	126 (37.5)	58 (69.88)	72 (28.02)	112 (69.14)
3	Do you think adverse drug reaction reporting is necessary?					
	a. Yes	416 (99.28)	333 (99.11)	83 (100)	254 (98.83)	162 (100)
	b. No	3 (0.72)	3 (0.89)	0	3 (1.17)	0
4	Do you think all healthcare providers should consider themselves professionally obliged to report ADRs?					
	a. Yes	390 (93.08)	309 (91.96)	81 (97.59)	235 (91.44)	155 (95.68)
	b. No	29 (6.92)	27 (8.04)	2 (2.41)	22 (8.56)	7 (4.32)
5	Do you think timely monitoring and reporting of ADR can significantly improve patient safety and reduce morbidity and mortality?					
	a. Yes	418 (99.76)	335 (99.70)	83 (100)	256 (99.61)	162 (100)
	b. No	1 (0.24)	1 (0.3)	0	1 (0.39)	0
6	Do you think ADR should be discussed during clinical posting/ward rounds?					
	a. Yes	407 (97.14)	325 (96.73)	82 (98.8)	249 (96.89)	158 (97.53)
	b. No	12 (2.86)	11 (3.27)	1 (1.2)	8 (3.11)	4 (2.47)
7	Do you think the ADR form is complex to fill?					
	a. Yes	170 (40.57)	133 (39.58)	37 (44.58)	96 (37.35)	74 (45.68)
	b. No	249 (59.43)	203 (60.42)	46 (55.42)	161 (62.65)	88 (54.32)
8	Do you think pharmacovigilance training/ awareness program should be conducted often?					
	a. Yes	407 (97.14)	327 (97.32)	80 (96.39)	250 (97.28)	157 (96.91)
	b. No	12 (2.86)	9 (2.68)	3 (3.61)	7 (2.72)	5 (3.09)
9	Which, according to you, is the preferred method for sending information regarding ADR?	a. Directly filling up the ADR form b. Telephone via the helpline number c. Via email/on the website d. Others				A-169 (40.33) C-86 (20.53) A+B + C-39 (9.31) B-37 (8.83) other combinations-88 (21)
10	What are the factors you think hinder healthcare providers from reporting ADRs?	a. Lack of time b. Lack of motivation/awareness c. Poor knowledge of the reporting procedure d. Nonavailability of ADR forms e. All of the above				E-256 (61.1) C-37 (8.83) B+C-35 (8.35) A+B + C-30 (7.16) Other combinations-61 (14.56)

ADR: Adverse drug reaction

ADR can significantly improve patient safety and reduce morbidity and mortality.

Practice-based questions

Table 4 shows the practice-related questions and their responses. It was seen that 92.84% are willing to report ADR but only 12.17% of students filled up an ADR form. Only 14.32% have attended training or awareness programs on PV and ADR reporting.

The mean KAP score was calculated as shown in Table 5. Thereafter, the difference between the mean scores was analyzed using Student's *t*-test. It was seen that the p-value was significant for attitude and practice among the UGs and PGs. However, the p-value was highly significant for KAP when the CBME and Old Curriculum were compared.

DISCUSSION

The major limiting factor associated with spontaneous reporting of ADR is under-reporting. The responsibility of PV must be shared by all the stakeholders, the participation of all HCPs being the vital force of the dynamics of this program. A constant vigilance on drug safety issues is always needed to promote better patient care [17].

Table 4: Comparison of the practice of undergraduate and postgraduate students, competency-based medical education, and Traditional curriculum

S. No.	Question	Frequency				
		Overall, n (%)	Professional qualification		Curriculum	
			Undergraduate, n (%)	Postgraduate, n (%)	CBME, n (%)	Traditional, n (%)
1	Have you ever seen a case of ADR during your ward/ clinical posting?					
	a. Yes	105 (25.06)	51 (15.18)	54 (65.06)	26 (10.12)	79 (48.77)
	b. No	314 (74.94)	285 (84.82)	29 (34.94)	231 (89.88)	83 (51.23)
2	Have you seen/actively participated in management of an ADR in your ward/clinical posting?					
	a. Yes	97 (23.15)	50 (14.88)	47 (56.63)	26 (10.12)	62 (38.27)
	b. No	322 (76.85)	286 (85.12)	36 (43.37)	231 (89.88)	100 (61.73)
3	Are you willing to report ADRs?					
	a. Yes	389 (92.84)	310 (92.26)	79 (95.18)	239 (93)	150 (92.59)
	b. No	30 (7.16)	26 (7.74)	4 (4.82)	18 (7)	12 (7.41)
4	Have you ever filled up an ADR form?					
	a. Yes	51 (12.17)	42 (12.5)	9 (10.84)	36 (14.01)	15 (9.26)
	b. No	368 (87.83)	294 (87.5)	74 (89.16)	221 (85.99)	147 (90.74)
5	Have you ever read any articles on prevention of Adverse Drug Reactions?					
	a. Yes	162 (38.66)	114 (33.93)	48 (57.83)	89 (34.63)	73 (45.06)
	b. No	257 (61.34)	222 (66.07)	35 (42.17)	168 (65.37)	89 (54.94)
6	Do you usually counsel a patient about possibility of the development of ADRs with drugs and instructed them to communicate the same with you if appears?					
	a. Yes	288 (68.74)	213 (63.39)	75 (90.36)	163 (63.42)	125 (77.16)
	b. No	131 (31.26)	123 (36.61)	8 (9.64)	94 (36.58)	37 (22.84)
7.	Have you ever attended training/awareness Program on Pharmacovigilance/ADR?					
	a. Yes	60 (14.32)	48 14.29)	12 (14.46)	43 (16.73)	17 (10.49)
	b. No	359 (85.68)	288 (85.71)	71 (85.54)	214 (83.27)	145 (89.51)
8	Have you seen any patients with serious adverse drug reaction being admitted in ICU?					
	a. Yes	85 (20.29)	50 (14.88)	35 (42.17)	36 (14.01)	49 (30.25)
	b. No	334 (79.71)	286 (85.12)	48 (57.83)	221 (85.99)	113 (69.75)
9	What are the source/sources you prefer for gathering information on ADR	a. Textbooks				A+B + D-91 (21.72)
		b. Medical journals				A+B + C-81 (19.33)
		c. Internet				A-60 (14.32)
		d. Product catalogs				B-47 (11.22)
		e. Please specify if any other				Other combinations 140 (33.41)
10	What are the measure/measures that can be practiced for improving Pharmacovigilance and ADR reporting?	a. Organizing CME, training and awareness programs on the topic				A+B + C+D + E-128 (30.55)
		b. Making ADR reporting compulsory				A-91 (21.72)
		c. Frequent reminders and drive from the ADR monitoring center				A+D + E-22 (5.25)
		d. Making the reporting procedure easy				D-21 (5.01)
		e. ADR forms should be made easily accessible				Other combinations 157 (37.47)
		f. Please suggest any other				

ADR: Adverse drug reaction

Table 5: Mean knowledge, attitude, and practice score of the participants (n=419)

Professional qualification	Mean±SD score		
	Knowledge	Attitude	Practice
Undergraduate students	7.68±1.60	9.07±0.85	4.61±1.57
Postgraduate students	7.34±1.59	8.75±0.67	6.33±1.57
p	>0.05	<0.05	<0.01
CBME	7.88±1.60	9.19±0.82	4.60±1.54
Traditional	7.20±1.54	8.73±0.76	5.52±1.82
p	<0.01	<0.01	<0.01

CBME: Competency-based medical education, SD: Standard deviation

In the present study, it is seen UGs have good knowledge of both PV and ADR. However, PG knowledge about ADRs (84.34%) is more compared to PV (69.88%). In the study done by Kulmi *et al*. [12], most of the UGs and post-graduates have good knowledge about both PV and ADR. Another study by Upadhyaya et al. [18] showed a lack of correct knowledge about ADR reporting and PV. When the observation was done based on the curriculum, it was seen that the knowledge about PV was more among CBME-curriculum students (87.16%) compared to the old curriculum (76.54%). This may be due to more coverage on the topic of PV in the CBME-based curriculum. Also, CBME students feel that the topic of PV covered in the curriculum is sufficient for reporting ADR in future practice.

However, 63.1% of UGs and only 32.53% of PGs have seen an ADR reporting form. Observation based on curriculum shows that a good number of CBME-based students (78.99%) have seen ADR-reporting form compared to 22.22% of old curriculum students. A good number of both UGs and PGs know about the types of ADRs that can be reported and the people who can report them. A maximum number of students feel that ADR –reporting is necessary and that healthcare providers should consider themselves obliged to report ADRs. A study done by Kunnoor *et al*. showed majority think that ADR reporting can bring significant difference to the community [19]. However even after a positive attitude towards PV and ADR reporting, in practice, only 12.5% of UGs and 10.84% of PGs have filled up an ADR form. When asked about factors that hinder them from reporting ADRs, maximum think that it is due to a combination of multiple factors like poor knowledge about the reporting procedure, lack of motivation/awareness, and lack of time. The majority of the students feel that organizing CME, training, and awareness programs can improve practice about PV and ADR reporting and so these should be conducted often. Some previously done studies found that the knowledge and attitude scores as well as ADR reporting were improved after educational interventions [3,20].

In our study, as a whole, the mean KAP score of attitude is better than the knowledge and practice scores. Maintenance of a similar attitude during the rest of professional life may lead to better practice of PV. The practice score of our study is better than other similar studies [2,12,13]. The KAP score of knowledge and attitude was significantly higher for CBME students compared to Old Curriculum.

CONCLUSION

Our study concluded that in terms of knowledge and attitude, both UG and PG students showed good responses. However, the same was not reflected in their practice. Educational interventions, training, and sensitization programs can play an important role in improving the practice because as future physicians, they carry a lot of responsibility toward preventing and reporting ADRs. However, an encouraging finding here has been that the current CBME curriculum has a positive impact on knowledge and attitude due to the emphasis given to this topic in the curriculum.

AUTHORS CONTRIBUTION

Conception/design: Dr. S Renuka Singh, Dr. Dwipen Khanikar, Dr. Pran Pratim Saikia, Dr. Diptimayee Devi. Provision of study material: Dr. S Renuka Singh, Dr. Dwipen Khanikar, Dr. Pran Pratim Saikia, Dr. Diptimayee Devi. Collection of data: Dr. S Renuka Singh, Dr. Dwipen Khanikar, Dr. Pran Pratim Saikia, Dr. Diptimayee Devi. Data analysis and interpretation: Dr. S Renuka Singh, Dr. Dwipen Khanikar, Dr. Pran Pratim Saikia, Dr. Diptimayee Devi. Manuscript writing: Dr. S Renuka Singh, Dr. Dwipen Khanikar, Dr. Pran Pratim Saikia, Dr. Diptimayee Devi. Final approval of manuscript: Dr. S Renuka Singh, Dr. Dwipen Khanikar, Dr. Pran Pratim Saikia, Dr. Diptimayee Devi.

CONFLICT OF INTEREST

None to declare.

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