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Original Research Article

Perceptions of undergraduate medical students of old traditional and new CBME curriculum about pharmacovigilance and adverse drug reactions reporting at a tertiary care teaching hospital: a comparative study

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ABSTRACT

Background: National pharmacovigilance program is an ongoing program to monitor the adverse drug reactions and reporting at the earliest. The effectiveness and success of any pharmacovigilance system depends highly on the participation of all health care professionals. As medical students are future health-care givers, this study is aimed to measure perceptions on Pharmacovigilance and ADR reporting among medical students of two different curriculum.

Methods: A validated and standardized KAP Questionnaire based cross sectional study. It consists of 22 questions divided into four sections of total of 22 items (six related to Personal details, eight related to knowledge, four related to attitude, and four related to practice) The filled questionnaires were collected and analyzed by MS excel

Results: A comparative sample of 100 from old (phase 4) and 100 from New CBME (phase 3) curriculum undergraduate medical students of Government Medical College are included in our study. The average score of phase 3 and phase 4 medical students for knowledge was 85.37% and 75.87%, for attitude was 95.5% and 84% and for practices was 88.75% and 67.5% respectively.

Conclusions: The overall knowledge, attitude and practices of new curriculum students found to be better than old curriculum students as CBME curriculum was introduced from the academic year 2019–2020 in all Medical Institutions of India to impart knowledge, communication and leadership skills using various teaching–learning methods among students.

Keywords: Perceptions, CBME curriculum, Adverse drug reaction, Pharmacovigilance

INTRODUCTION

Medication safety and pharmacovigilance remains an important subject and discipline worldwide. The world health organization (WHO) defines pharmacovigilance (PV) as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.¹ WHO established its Programme for International Drug Monitoring in response to the thalidomide disaster

detected in 1961. The aims of PV are to enhance patient care and patient safety in relation to the use of medicines; and to support public health programmes by providing reliable, balanced information for the effective assessment of the risk-benefit profile of medicine. Adverse drug reactions (ADRs) are noxious, undesirable and unintended effects of drug administered at doses used for prophylaxis, diagnosis or therapy, and may be the major cause of morbidity, mortality and also increases the cost of the healthcare of the patient, health institutions as well as community.² Recent epidemiological studies estimated

that ADRs are fourth to sixth leading cause of death.³ According to recent studies the incidence of ADRs fluctuates between 4.6% and 17.6% in all hospitalizations and nearly 80% of medical expenses arise from ADRs, ADRs also seriously affect the quality of life of patients.⁴ The major limitation associated with spontaneous ADR reporting system is underreporting.⁵ Underreporting of ADRs is the biggest problem experienced globally.⁶ To detect and spontaneously report ADR and to ensure drug safety, the Government of India initiated the PV Program of India in July 2010. The Ministry of Health and Family Welfare, Government of India recasted PvPI on April 15 2011 shifting the National Coordination Centre from All India Institute of Medical Sciences (AIIMS), New Delhi to IPC, Ghaziabad. National Pharmacovigilance Week was celebrated from September 17th to 23 September.¹¹ The theme for 2022 year is "pharmacovigilance: a step towards patient safety". Since the launch of Pharmacovigilance program of India, medical council of India (MCI) mandated the implementation of ADR reporting in all the medical colleges to minimize the problem of underreporting. Medical colleges were informed to conduct regular workshops to enhance knowledge on ADR reporting voluntarily. In comparison to the old traditional curriculum, CBME needs experting the subject based on the competencies for theory, practical classes, small group discussions (SGD), and self-directed learning (SDL). Common topics across various pre-clinical, para-clinical, and clinical departments are supposed to be addressed through nesting, horizontal integration (HI), and vertical integrations (VI). There are topics, like P-drugs, adverse drug reaction (ADR) reporting, prescription audits, interaction with pharmaceutical representative etc. introduced especially in practical syllabus that requires assessment of skills. Therefore, in this study, we aimed to compare knowledge, attitude and practices among medical students from the two different curriculum on Pharmacovigilance and ADR reporting.

METHODS

Study design and duration

A cross-sectional, questionnaire based study. Duration of study is 4 months in the month of September to December 2022.

Sample size

Total 200 undergraduate medical students, of which a comparative sample of 100 from Phase 4 (Old curriculum) and 100 from Phase 3 (New curriculum) medical students of Government Medical College.

Inclusion and exclusion criteria

Inclusion criteria were: Age 18-25 years of both sexes and willing to give consent for the study. Exclusion criteria were; Unwilling to give consent for the study.

Procedure

The study was conducted at Government Medical College in Nizamabad, with a total duration of 4 months from September to December 2022. The target population of our study were the under graduate medical students of phase 3 (New CBME curriculum) and phase 4 (Old curriculum) who were already exposed and familiar with adverse drug reactions and pharmacovigilance. Informed consent is taken from students who are willing to participate in the study, after explaining the clinical study protocol in detail. Data is collected by using a structured and validated questionnaire (Google forms). These questions were designed based on earlier studies for assessing KAP of ADR reporting.^{8,9} The survey questionnaire consists of four parts and contains a total of 22 items (six related to Personal details, eight related to knowledge, four related to attitude and four related to practices). To test the validity and reliability the questionnaire was pilot-tested by administering it to a sample of 10 (10% of sample size) medical students, 5 in each group. Pilot study revealed that it took 5- 6 min to complete the whole questionnaire.

Measures

Independent variables: Independent variables comprised of participants personal details such as age, gender, year of study. Dependent variables: The dependent variables of this study are Knowledge, Attitude, Perception (KAP). The questionnaire consisted of a total of 22 questions. (Q1-Q22). The first six questions (Q1-Q6) are related to personal details, next eight questions (Q7-14) assessed the knowledge towards pharmacovigilance with multiple options and only one single correct option. The next eight questions (Q15-Q22) were directed to understand the attitude of the students towards pharmacovigilance. A score of 1 was given for each correct answer and 0 for the wrong answer. The final 4 questions (Q19-Q22) were related to the practice of ADR reporting and assessed if they had witnessed an ADR, seen an ADR reporting form and if they had identified/discussed/reported an ADR.

Statistical analysis

The results were entered and analyzed question wise and their percentage and average score are used for descriptive statistics with the help of Microsoft Excel 2010 spread sheet software.

RESULTS

A total of 200 medical students were participated in our study, 100 were from Phase 3 (New) and 100 were from Phase 4 (Old curriculum). Among the participants, the majority were Females (N=144, 67%), Male (N=56, 33%). Majority of the participants (N=188, 87.4%) were in the age group of 19 to 21 years. The details depicting demographic variables of medical students are listed in (Table 1). A total of 200 medical students were participated in our study, 100 were from Phase 3 (New)

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Table 1: Depicting personal characteristics of participants (n=200).

Personal characteristics of the participants	N	%
Age (years)	19-21	188 94
	>22	12 6
Gender	Male	56 28
	Female	144 72
Year of Study	Phase 4	100 50
	Phase 3	100 50

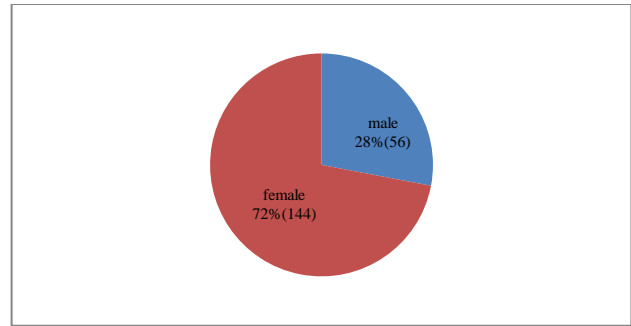


Figure 1: Gender distribution among medical student.

Analysis of knowledge

The details regarding the responses of medical students for knowledge-based questions are listed in (Table 2).

Table 2: The details regarding the responses of medical students for knowledge based questions.

Q. no.	Knowledge questions	Responded correctly Frequency (%)	
		Phase 3 (New CBME Curriculum) (N=100)	Phase 4 (Old Curriculum) (N=100)
Q7	Define Pharmacovigilance?	95 (95)	89 (89)
Q8	Define Adverse Drug Reaction	83 (83)	70 (70)
Q9	Do you believe all drugs available in the market are safe?	99 (99)	92 (92)
Q10	Are you aware of casualty assessment of Adverse drug reaction?	79 (79)	60 (60)
Q11	Do you know different types of ADR?	87 (87)	78 (78)
Q12	Can patient were allowed to report adverse drug reactions through mobile?	48 (48)	42 (42)
Q13	ADR should be reported only when they are?	92 (92)	79 (79)
Q14	Is it mandatory to have pharmacovigilance unit in every medical college?	100 (100)	97 (97)

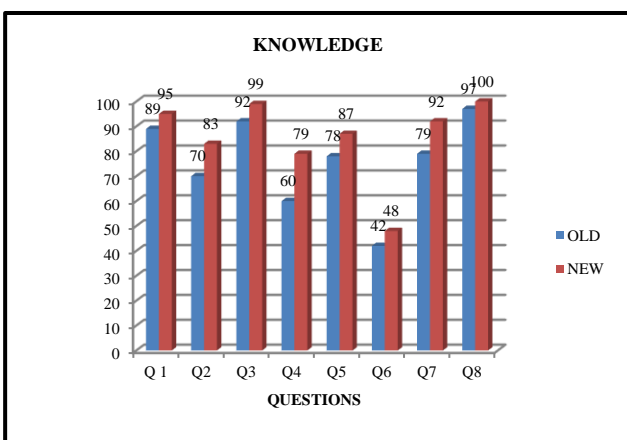


Figure 2: Bar diagram representing responses of medical students for knowledge towards Pharmacovigilance and ADRs reporting.

Among the respondents, 95% of phase 3 and 89% of Phase 4 medical students have good knowledge on PV which is more than ADR. 99% of Phase 3 and 92% of Phase 4

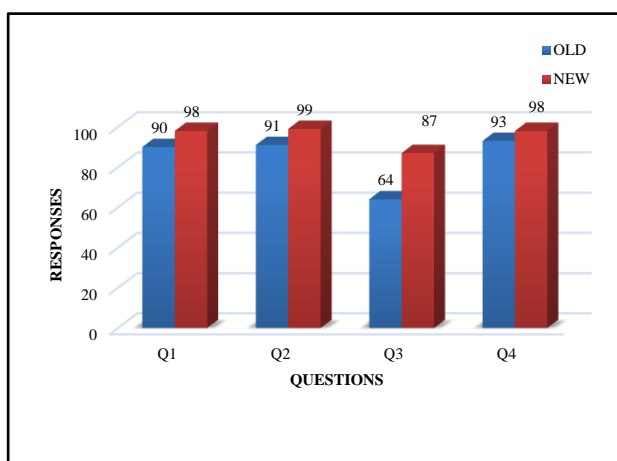
medical students believed that all the drugs available in market are not safe. 79% and 87% of Phase 3 and 60% and 78% of Phase 4 medical students were aware of casualty assessment of Adverse drug reaction and different types of ADR. 100% Phase 3 and 97% Phase 4 medical students agreed that it is mandatory to have pharmacovigilance unit in every medical college. Difference in Knowledge score among two groups is shown in (Figure 2).

Analysis of attitude

Total 98% of Phase 3 and 90% of Phase 4 medical students felt that Pharmacovigilance should be taught in detail to health care professionals. 99% of Phase 3 and 91% of Phase 4 medical students agreed that reporting of ADR is necessary for all health care professionals. 87% and 98% of Phase 3 and 64 % and 93% of Phase 4 medical students agreed that they are adequately trained on how to report ADR form and reporting will benefit patients. The details regarding the responses of the medical students for Attitude-based questions are listed in (Table 3).

Table 3: The details regarding the responses of medical students for attitude-based questions.

Q. no.	Attitude questions	Responded correctly Frequency (%)	
		Phase 3 (New CBME Curriculum) (N=100)	Phase 4 (Old Curriculum) (N=100)
Q15	Do you think Pharmacovigilance should be taught in detail to health care professionals.	98 (98)	90 (90)
Q16	Do you think reporting of ADR is necessary for all health care professionals.	99 (99)	91 (91)
Q17	Do you feel that you are adequately trained on how to report ADR form	87 (87)	64 (64)
Q18	Do you think ADR monitoring and reporting will benefit patients.	98 (98)	91 (91)

**Figure 3: Bar diagram representing responses of medical students for attitude towards Pharmacovigilance and ADRs reporting.**

Analysis of practices

There were four practice-related questions. 94% and 75% of Phase 3 and 75% and 55% of Phase 4 medical students seen the ADR reporting form and ADR in patients during your postings. 96% of Phase 3 and 85% of Phase 4 medical students are willing to participate education in PV and ADR reporting system. The details regarding the responses of the medical students for Practices based questions are listed in (Table 4).

DISCUSSION

Spontaneous reporting of ADRs is an important responsibility of all health care workers such as doctors (undergraduate and postgraduate), nurses, pharmacist, and even patients. A constant vigilance on drug safety issues is always needed to promote better patient care.¹⁰

Table 4: The details regarding the responses of medical students for practice based questions.

Q. no.	Practice questions	Responded correctly Frequency (%)	
		Phase 3 (New CBME Curriculum) (N=100)	Phase 4 (Old Curriculum) (N=100)
Q19	Have you ever been trained on how to report an ADR form in your college curriculum.	90 (90)	55 (55)
Q20	Have you ever seen the ADR reporting form?	94 (94)	75 (75)
Q21	Have you ever seen any ADR in patients during your postings?	75 (75)	55 (55)
Q22	If you offered an opportunity to undertake education in PV and ADR reporting system, would you be willing to participate.	96 (96)	85 (85)

It was seen that the average knowledge score on PV was more among CBME-curriculum students (85.37%) compared to the old curriculum (75.87%) as they are exposed to continuous sensitization on ADR reporting and pharmacovigilance in Practicals and continuous medical education (CME). In the study done by Kulmi et al most of the UGs and post-graduates have good knowledge about both PV and ADR.¹¹ Another study by Upadhyaya et al showed a lack of correct knowledge about ADR reporting

and PV.¹² A good number (87%) of CBME-based students know different types of ADR compared to 78% of old curriculum students. Total 87% of CBME based students felt that they are adequately trained on how to report ADR form when compared to 64% in old curriculum students. A study done by Kunnoor et al showed majority think that ADR reporting can bring significant difference to the community 75% of CBME students saw ADR in their postings and reported while only 55% of old curriculum students have seen ADR, a noteworthy finding of this

study.¹³ Medical colleges were informed to conduct regular workshops to enhance knowledge on ADR reporting voluntarily. Some previous studies found that the knowledge and attitude scores as well as ADR reporting were improved after educational interventions.¹⁴ There are enormous studies to assess the KAP of healthcare professionals towards pharmacovigilance and ADR reporting but there are no studies among the undergraduate medical students of two different curriculum to assess their perceptions.¹⁵⁻¹⁷

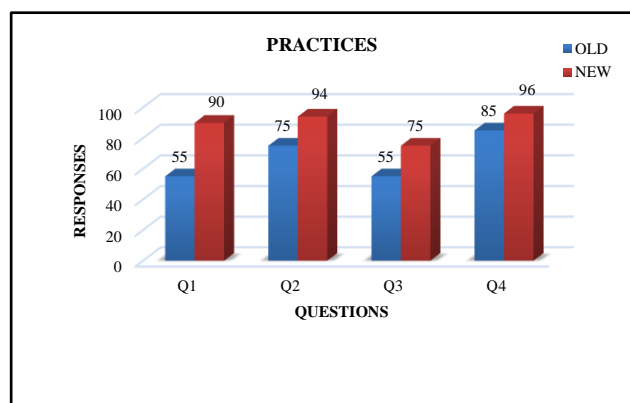


Figure 4: Bar diagram representing responses of medical students for practices towards Pharmacovigilance and ADRs reporting.

CONCLUSION

The overall knowledge, attitude and practices of new curriculum students found to be better than old curriculum students as CBME curriculum was introduced from the academic year 2019–2020 in all Medical Institutions of India to impart knowledge, communication and leadership skills using various teaching–learning methods among students.

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

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