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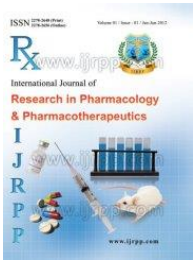

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Educational intervention impact on pharmacovigilance and ADR reporting among Pharm D students

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ABSTRACT

Purpose

Pharmacovigilance plays a significant role in identifying adverse drug reactions (ADRs). In India, lack of knowledge regarding ADR reporting is one of the major causes for underreporting of ADRs. Hence the present study aimed to evaluate the knowledge, attitude and practice (KAP) among Pharm D students before and after educational intervention.

Methods

A cross-sectional and validated questionnaire-based study was conducted among Pharm D students to assess the level of KAP on Pharmacovigilance and ADR reporting and compared the same after the educational intervention. Scoring was done for the questions. Results were compared by t-test.

Results

Among 197 participants 108 were male and 89 female. The improvement in knowledge related questions like functions, location of PvPI, WHO causality scales, timing of SAE(serious adverse event) reporting, methods employed by pharmaceutical companies to detect ADRs and people involved in reporting ADRs was statistically significant ($p<0.01$). Majority of the participants agreed that pharmacovigilance should be added in their curriculum and had come to know that there is no need to consult a physician before reporting.

Conclusion

In India, as Pham D is an emerging and clinically oriented course, educational interventions if held regularly, can help to improve knowledge and minimize underreporting of ADRs among healthcare professionals.

Keywords: Adverse drug reaction, Pharmacovigilance, Educational intervention, Pharm D students

INTRODUCTION

Worldwide, one of the most important causes for morbidity and mortality is drug-related problems especially ADRs [1]. As per World Health Organization (WHO), ADR is defined as "any noxious and unintended response to a drug, which occurs at doses normally used in humans for prophylaxis, diagnosis and treatment of the disease or for the modification of physiological functions [2]. ADRs reduce the quality of life and increase hospitalization. A South Indian study revealed that ADRs accounted to 0.7% of the total hospital admissions and 1.8% of total ADRs lead to death [3].

The monitoring and reporting of ADRs is crucial to prevent or minimize ADR related harm to patients [4]. The etymological roots for the word "Pharmacovigilance" is Pharmakon (Greek word for 'drug') and vigilare (Latin word for 'to keep watch') [5]. WHO defines Pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems, particularly long term and short term adverse effects of medicines"[6]. To promote drug safety, WHO has started International Drug Monitoring in 1961, and after that, it promoted Pharmacovigilance programme at country level in collaboration with International Drug Monitoring, Uppsala [7]. The Uppsala Monitoring Centre (UMC), Sweden maintains the international database of ADR reports received from different countries. In India, the National Pharmacovigilance Programme was initiated in the year 2004 for ADR monitoring, and now it is renamed as Pharmacovigilance Programme of India (PvPI).

PvPI was started in July 2010 by Central Drugs Standard Control Organization (CDSCO) under the aegis of the Ministry of Health & Family Welfare (MoHFW), at All India Institute of Medical Sciences (AIIMS), New Delhi as the National Coordinating Centre (NCC). The NCC was shifted from AIIMS to Indian Pharmacopoeia Commission (IPC), Ghaziabad on 15th April 2011. PvPI encourages all health care professionals to report all types of suspected ADRs irrespective of whether they are known or unknown, serious or non-serious, frequent or rare [8]

In Pharmacovigilance programme the main problem encountered is underreporting [9]. ADR reporting rates in India is below 1% [10]. The culprits for underreporting are inadequate funds, lack of trained staff and awareness about detection, communication and spontaneous reporting [11].

Doctor of Pharmacy (Pharm. D) is an emerging course introduced by the Pharmacy Council of India (PCI) in 2008. The main goal of this course is to provide better health care needs to the community. This course has five years of academic study, followed by one year of internship. Pharm D course is mainly patient centered, they conduct counseling and inform them about the dose, time and route of medication, explain about mechanisms of how a drug acts on the body, its side effects, ADRs and emphasize on life style modifications [13]. Many studies have been conducted in India about Pharmacovigilance relating to knowledge, attitude and practice (KAP) towards ADR reporting among health care professionals and they suggested that there is a greater need to create more awareness and educational intervention to minimize underreporting [14-16]. As Pharm D course is mostly patient-centered curriculum and reduces the work load of physicians, this study was undertaken among Pharm D students. The main objective of the study was to know the KAP of Pharm D students and the impact of an educational intervention on Pharmacovigilance and ADR reporting.

MATERIALS AND METHODS

The present study was a cross sectional, questionnaire based study conducted at Vishwabharathi Institute of Pharmaceutical Sciences, Guntur, by the Department of Pharmacology, Guntur Medical College which has been running the ADR Monitoring Centre (AMC) under the PvPI. Before the start of the study, approval from the Institutional Ethics Committee was obtained. All the Pharm D students, willing to give written informed consent were included in the study. A predesigned, structured questionnaire was used to assess the KAP of Pharmacovigilance and ADR reporting among Pharm D students. The questionnaire was pretested on a small group of students by doing a pilot study. The internal consistency reliability of Cronbach's alpha coefficient was 0.79.

The questionnaire consists of demographic details, knowledge of participants regarding Pharmacovigilance and ADR reporting, attitude towards the Pharmacovigilance and practical aspects

of ADR reporting. A pretest was conducted to identify their initial KAP on Pharmacovigilance and ADR reporting. An interactive educational intervention was provided by Pharmacologists and technical associate of the PvPI. The educational intervention consisted of lectures on Pharmacovigilance and its importance, role of health care professionals in ADR reporting, causality assessment methods, vigiflow database, Haemovigilance Programme of India (HvPI) and its importance and hands-on training of ADR form filling. All the participants were given the same questionnaire at the end of interactive educational session. Based on the number of correct answers, scoring was done for both pre and posttest. In knowledge, 14 questions were selected for scoring, and 1 point was given for each correct answer. The maximum score that could be obtained was 14 for each participant in either pre or posttest.

STATISTICAL ANALYSIS

Data were analyzed using descriptive statistics. The comparison of KAP on Pharmacovigilance and ADR reporting among Pharm D students before and after the intervention was done by t-test and p-value < 0.05 was considered to be statistically significant.

RESULTS

In this cross-sectional study, a total of 197 Pharm D students participated and answered the questionnaire before and after the educational intervention. Among 197 participants, 108 (55 %) were male, and 89(45 %) were female. The details are given in table 1.

Table 1: Demographic details of the participants

Characteristics	n (%)
Male	108 (55%)
Female	89 (45%)
Mean Age	19.06 years

n = number of participants

Evaluation of knowledge towards Pharmacovigilance and ADR reporting

The answers seeking the knowledge of the participants towards Pharmacovigilance and ADR reporting are depicted in Table 2. Before the educational intervention, even though, majority (83%) of the participants were aware of the term Pharmacovigilance, only 40% of participants had knowledge about the functions of Pharmacovigilance, 49% were aware of the location of NCC for PvPI in India, 16% had knowledge on the location of UMC and 23% were aware of the Chairman of PvPI. The participants had poor knowledge regarding incorrect ADR reporting system in different countries, the idea regarding most common method employed by the pharmaceutical companies to monitor ADRs of new drugs, who can report ADRs, the composition of PvPI members, scales used in causality assessment, and the time period within which a SAE should be reported. Majority of the participants (93%), were aware of the location of nearest ADR monitoring Centre (AMC), 91% of them knew about WHO online database for uploading ADR forms in India and 86% of them produced correct response regarding the expansion of Individual Case Safety Report Form (ICSR).

Table 2: Evaluation of knowledge of Pharmacovigilance and ADR reporting before and after the educational intervention

S.No	Knowledge related questions	Pretest correct Response n (%)	Posttest correct response n (%)
1	Definition of Pharmacovigilance	164 (83.3)	183 (93)
2	Functions of Pharmacovigilance	79 (40)	164 (83)
3	Location of NCC for PvPI in India	96 (49)	157 (80)
4	Controller for PvPI	100 (51)	143 (73)
5	Location of UMC	31(16)	117 (56)

6	Chairman of PvPI	46 (23)	73 (37)
7	Location of nearest AMC	183 (93)	190 (97)
8	Incorrect ADR reporting system	02 (1)	102 (52)
9	NCC for biological and vaccines is controlled by	152 (77)	151 (77)
10	WHO online database - India	180 (91)	180 (91)
11	Composition of PvPI members	05 (3)	107 (54)
12	Who can report ADRs?	05 (3)	147 (75)
13	Expand the acronym ICSR	170 (86)	187 (95)
14	The scale used in causality assessment of ADRs	4 (2)	97(49)
15	In India, SAE should be reported within	21 (11)	171 (87)
16	The method employed by Pharmaceutical companies to monitor the ADRs of new drugs	5(2.5)	153(77.7)

n = number of participants

Evaluation of attitude and practice towards Pharmacovigilance and ADR reporting

A total of three questions sought information regarding the attitude and practice of Pharmacovigilance and ADR reporting. The answers are depicted in Table 3. Before the educational intervention, only 11% of the participants felt that pharmacists need not consult physicians before reporting ADRs. Majority of them agreed that ADR reporting increases patient safety, and it should be taught in detail to all healthcare professionals.

Table: 3. Evaluation of Attitude and practice of Pharmacovigilance and ADR reporting

S.No	Attitude and Practice related questions	Pretest correct Response n (%)	Posttest correct Response n (%)
1	Do you think ADR reporting will increase patient safety	192(97.5)	195(99)
2	ADR reporting should be taught to all health care professionals in curriculum	161(81.7)	182(92.4)
3	Do you think a pharmacist should consult the physician before reporting ADRs?	22(11)	110(55.8)

n= number of participants

As depicted in Table 4, after the educational intervention, there was an overall significant improvement ($p < 0.01$) in knowledge related questions and for questions relating to attitude and practice, the improvement was not statistically significant (p=0.1)

Table 4.Differences in pre and posttest KAP scores

	Pre-test		Post-test			
Domain	**Mean**	**SD**	**Mean**	**SD**	**t value**	**p-value**
Knowledge	6.07	1.56	10.39	2.48	2.89	<0.01*
Attitude and practice	1.9	0.485	3.24	0.771	1.23	0.1

*p<0.05, calculated by t-test, SD: Standard deviation

DISCUSSION

The aim of Pharmacovigilance is to ensure safe and rational use of medicines, after their release into the market. Spontaneous ADR reporting plays a key role in Pharmacovigilance programme. In India, one of the most important reasons for underreporting of ADRs is lack of awareness among healthcare professionals. This study was conducted on Pharm D students to assess their KAP about

Pharmacovigilance and ADR reporting and change in the same after educational intervention as Pharm D course is clinically oriented.

In our study, after the educational intervention, more than 80% of the participants were able to respond correctly for the questions on the definition, functions of Pharmacovigilance, location of nearest AMC and timeframe for reporting of SAE. Similar results were observed in the study done by Goel et al. [17]. In the present study, more than 75% of the participants were able to give correct response to the questions regarding the location of NCC for PvPI and who can report ADRs. This finding is in contrast to a study done by Ganesan et al [18]. In our study, after the training program the majority of the participants (>75%) improved their knowledge on reporting of ADRs of new drugs to relevant authorities.

From our study it was clear that, even though, most of the participants had better knowledge on WHO online database for uploading ADR forms in India, the improvement regarding the location of UMC, causality assessment scales and ADR reporting systems in different countries was moderate after the training program, which coincides with the findings of Shalini and Mohan et al. [19]. These drawbacks can be overcome by conducting more workshops, conferences, and CMEs related to Pharmacovigilance among healthcare professionals [20].

In the present study, the participants had a positive and encouraging attitude towards ADR reporting, and the majority of them agreed on the fact that ADR reporting increases patient safety and that adding an educational intervention in their curriculum definitely improves the attitude and practice of the health care professionals. There was a false belief that pharmacists should consult a physician before reporting any ADR, which was one of the reasons for underreporting. This wrong idea was cleared to a certain extent by our educational program.

In India, underreporting is because, all ADRs are considered not serious, already known, uncertainty concerning the causal relationship between the ADR and the drug, lack of time, lack of interest, fear of legal issues, considering reporting ADRs as less important task and lack of understanding in spontaneous reporting system [21]. All these drawbacks need to be addressed and minimized by conducting regular CMEs and workshops to the health care professionals.

CONCLUSION

Pharm D is a newly launched curriculum in India; it will take time to get well established. Our study suggested that though they had insufficient knowledge and awareness about Pharmacovigilance and ADR reporting and they were eager to learn about ADR reporting. As Pharm D students also play a major role in the health care system, educating and updating their knowledge on Pharmacovigilance and ADR reporting will minimize underreporting of ADRs in our country to some extent.

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