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RESEARCH ARTICLE

Knowledge, awareness, and practice of pharmacovigilance among health-care providers at a tertiary care hospital – A questionnaire-based study

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ABSTRACT

Background: Adverse drug reactions (ADRs) are among the leading causes of morbidity and mortality globally. The school has recently been recognized as an ADR monitoring center under the National Pharmacovigilance Program. This study was conducted to assess the knowledge, attitude, and practice (KAP) about pharmacovigilance among health-care providers and medical students of the school and associated hospitals. **Aims and Objective:** The aim of the study was to assess knowledge awareness and practice of pharmacovigilance among health-care providers at a tertiary care hospital Vijayanagar Institute of Medical Sciences, Ballari. **Materials and Methods:** A cross-sectional, questionnaire-based survey was conducted. A pretested and validated questionnaire for assessing the KAP of pharmacovigilance among the health-care providers and medical students was used. **Results:** The knowledge and attitude of health-care providers toward reporting of ADRs was satisfactory. Awareness about the pharmacovigilance activities within the institution was less as only 27% were aware and quite 90% of participants agreed that reporting of ADRs is vital, should be made mandatory, and believed that it might help patient safety within the future. However, 50% of health-care providers reported regular ADRs. The explanations for not reporting ADRs included difficulty in knowing whether an ADR has occurred or it is a symbol of disease, and lack of your time, ADR is already documented, managing the patient is more important, or ADR is mild. Training on the way to report an ADR during their professional course was received by 60.4% of the health-care providers. The pharmacists were less aware, whereas the medical students were cognizant about the importance of pharmacovigilance. **Conclusion:** There is a requirement to enhance the culture of reporting ADRs among the health-care providers within the institute. The primary step would be to extend awareness about facilities and processes *in situ* for reporting ADRs. Incorporation of coaching about pharmacovigilance within the curriculum of all the health-care providers may help in increasing awareness and practice of reporting ADRs.

KEY WORDS: Attitude; Health-care Providers; Knowledge; Pharmacovigilance; Practice

INTRODUCTION

Adverse drug reactions (ADRs) represent a serious burden on society, leading to significant morbidity, mortality, and health-care costs[1] a study from India revealed that around 6% of hospital admissions are estimated to flow from ADRs and about six to 15 of hospitalized patients experience serious ADRs.[2] Furthermore, a Swedish study estimated that 3.1% of deaths within the general population were attributed to ADRs.[3]

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Pharmacovigilance has been defined as "the science and activities concerning the detection, assessment, understanding, and prevention of adverse effects or the other drug-related problem."[4] In 2010, the Pharmacovigilance Programme of India (PvPI) was initiated for monitoring

ADRs within the country. The larger goal of the program is to safeguard public health by assuring the security of medicinal products. Doctors, nurses, and pharmacists are key professionals involved in prescribing, dispensing, administering, storage, and disposal of medicines. Their role in strengthening the pharmacovigilance program by reporting ADRs that might help increase patient safety cannot be overemphasized. Underreporting of ADRs may be a common problem within the pharmacovigilance program.[5] Findings from various studies have revealed that ADR reporting by health-care providers is linked to their knowledge, attitude, and practice (KAP) about pharmacovigilance.[6]

Vijayanagar Institute of Medical Sciences (VIMS) Medical College has been recognized as an ADR monitoring center (AMC) under the PvPI. The hospital caters to about a million patients in outpatients and 70,000 inpatients annually. Reporting of ADRs by health-care providers is being encouraged by sensitizing programs. There is no availability of knowledge on the KAP of pharmacovigilance among the health-care providers and medical students within the institute. This data would help to enhance the standard of the prevailing pharmacovigilance program within the institute. Hence, the present study was conducted to assess the KAP about pharmacovigilance and implementation of the program within the institute among the health-care providers and medical students in VIMS Ballari.

MATERIALS AND METHODS

After approval from the Institutional Ethics Committee of VIMS, Ballari, the study was carried out for a period of 2 months, i.e., December 2019 and January 2020.

This is a prospective cross-sectional pre-validated questionnaire-based study conducted at VIMS, Ballari, for a period 2 months (December 2019 and January 2020). A questionnaire was developed focusing on the medical pharmacovigilance concept, their knowledge, awareness, and practices toward it, this questionnaire was further refined based on the pilot survey conducted in a small group of postgraduate students and the final questionnaire was formed.

A pre-tested, structured, and validated questionnaire was utilized in the study. The questionnaire was validated by face and content validation. The questionnaire was divided into the subsequent parts: (i) Demographic characteristics, (ii) KAP of pharmacovigilance, (iii) and suggestions on possible ways to enhance pharmacovigilance. There have been 13 questions concerning the essential knowledge and knowledge about pharmacovigilance, nine questions concerning attitude, and seven questions concerning perception regarding the identification of ADR and its reporting.

Health-care providers, including doctors, nurses, pharmacists, and medical students (third semester onward and interns) working within the hospital, were included in the study and those who were not willing to participate were excluded from the study.

The health-care providers got the questionnaire after explaining to them the aim of the study. They were requested to finish the questionnaire and provides it back immediately to maximize the response rate.

Data analysis was administered using an MS Excel spreadsheet and the percentage of observations was noted.

RESULTS

The questionnaire was administered to 90 doctors and nurses each, 40 pharmacists, and 250 medical students. The sample size was of convenience. There are 50 pharmacists working in the hospital and all were included in the study. Of the total respondents, 49.4% were females and 63.8% were within the age group of 21–30 years.

More than 70% of health-care providers were conscious of what's pharmacovigilance, the pharmacovigilance program being programmed by the Government of India, the tactic employed by pharmaceutical companies to watch ADRs, and therefore the ADR reporting system in India also as within the hospital [Table 1]. About 50–60% of participants knew who all can report ADRs, the organization liable for ADR reporting in India and therefore the existence of the Committee for Pharmacovigilance within the institution. Awareness about the pharmacovigilance activities within the institution was less. However, 50% of participants were conscious of the designated officer for it, training workshops, and sources of data available within the campus to extend awareness about ADRs, and only 27% knew about the facilities available to report ADRs within the institution [Table 1].

The majority (98.6%) of participants agreed that reporting of ADRs is vital and quite 90% of participants agreed that reporting of ADRs should be mandatory. Reporting of ADRs was believed to be the responsibility of a health-care provider by 90% and 89% agreed that ADR reporting may be a professional obligation. They opined that teaching about pharmacovigilance activities during their education and training may improve the culture of reporting of ADRs. Over 90% of health-care providers believed that reporting of ADRs would help patient safety within the future. The bulk (70%) agreed that a lot of ADRs are avoidable. About 59% were in agreement that each one ADRs, even the less serious, got to be reported [Table 2].

Lesser than 50% of health-care providers reported having come across ADRs, keeping records of ADRs or reporting to the AMC in the college [Table 3]. Among the reasons for not reporting ADRs included the following: (i) Difficulty in knowing whether an ADR has occurred or it is a symptom

of disease (22.8%), (ii) lack of time (19.8%), (iii) ADR is already well known (17.8%), and (iv) managing the patient is more important (14.2%) or ADR is mild (12.4%) [Figure 1]. It was found that 59.6% of respondents try to prevent ADRs and only 30.6% had come across drug alerts. Training on how to report an ADR during their professional course had been received by 60.4% of the health-care providers.

DISCUSSION

Safe use of medicines is an important component of quality health care. Thus, the use of medicines must be monitored continuously through an efficient pharmacovigilance system. Reporting of ADRs by all involved within the use of medicines, which incorporates doctors, nurses, pharmacists,

Table 1: Knowledge and awareness of health-care providers about pharmacovigilance

Questions	Correct response				
	Pharmacists *n* (%)	Nurses *n* (%)	Doctors *n* (%)	Students *n* (%)	Total *n* (%)
The detection, assessment, understanding, and prevention of ADRs are pharmacovigilance	20 (40%)	72 (72)	74 (74)	230 (92)	396 (79.2)
Pharmacovigilance includes problems related to drugs, herbals, vaccines, and medical devices	0	53 (53)	63 (63)	160 (64)	276 (55.2)
Post-marketing surveillance is the most common method used by the pharmaceutical companies to monitor the ADR of a newly launched product in the market	22 (44)	62 (62)	77 (77)	212 (84.8)	373 (74.6)
The current pharmacovigilance program running by the Government of India is the Pharmacovigilance Programme of India	28 (56)	52 (52)	70 (70)	216 (86.4)	366 (73.2)
The international organization responsible for ADR monitoring is Uppsala Monitoring Centre	13 (26)	21 (21)	32 (32)	21 (8.4)	87 (17.4)
The organization in India responsible for ADR monitoring is Indian Pharmacopoeia Commission	17 (34)	45 (45)	54 (54)	173 (69.2)	289 (57.8)
Doctors and paramedic staff both are responsible for reporting of ADRs in a hospital	30 (60)	80 (80)	0	191 (76.4)	301 (60.2)
ADR reporting system in India is suspected ADR reporting form	21 (42)	62 (62)	62 (62)	216 (86.4)	361 (72.2)
Presence of ADR reporting system in your hospital, institution, ward, or pharmacy	9 (18)	64 (64)	74 (74)	233 (93.6)	380 (76)
Committee for Pharmacovigilance in the college (Vijayanagar Institute of Medical Sciences)	9 (18)	55 (55)	57 (57)	194 (77.6)	315 (63)
Designated officer for pharmacovigilance activities in your department	6 (12)	40 (40)	50 (50)	139 (55.6)	235 (47)
Facilities available at the institution/hospital level to report ADRs	4 (8)	25 (25)	33 (33)	73 (29.2)	135 (27)
Sources of information available to increase awareness about ADR in the campus	6 (12)	42 (42)	44 (44)	136 (54.4)	228 (45.6)
Awareness about training workshops on pharmacovigilance and ADR in the past 5 years in the campus	2 (4)	28 (28)	38 (38)	148 (59.2)	216 (43.2)

ADRs: Adverse drug reactions

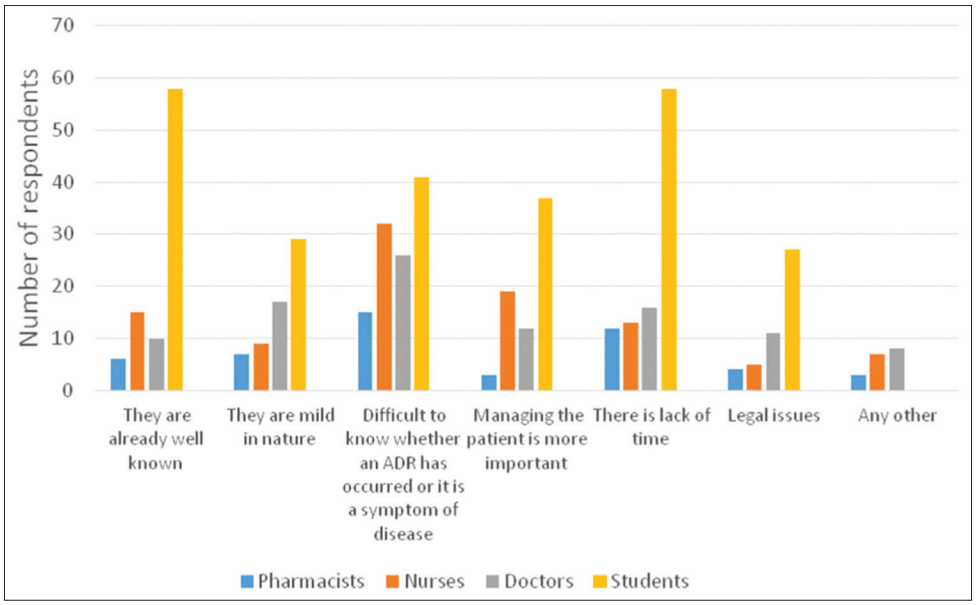

Figure 1: Reasons for not reporting adverse drug reactions

Table 2: Attitude of health-care providers toward pharmacovigilance

Questions	Response	Pharmacists *n* (%)	Nurses *n* (%)	Doctors *n* (%)	Students *n* (%)	Total *n* (%)
Reporting of ADRs is important	Agree	49 (98)	99 (99)	96 (96)	249 (99.6)	493 (98.6)
	Neutral	0	0	2 (2)	1 (0.4)	3 (0.6)
	Disagree	1 (2)	0	2	0	3 (0.6)
It is the responsibility of a health-care provider to report the ADR	Agree	45 (90)	94 (94)	90 (90)	224 (89.6)	453 (90.6)
	Neutral	3 (6)	2 (2)	6 (6)	13 (5.2)	24 (4.8)
	Disagree	2 (4)	4 (4)	4 (4)	13 (5.2)	23 (4.6)
Reporting of ADRs should be mandatory	Agree	43 (86)	91 (91)	91 (91)	236 (94.4)	461 (92.2)
	Neutral	3 (6)	4 (4)	6 (6)	11 (4.4)	24 (4.8)
	Disagree	4 (8)	5 (5)	3 (3)	3 (1.2)	15 (3)
Reporting of an ADR is a professional obligation	Agree	40 (80)	85 (85)	80 (80)	196 (78.4)	401 (80.2)
	Neutral	5 (10)	5 (5)	15 (15)	27 (10.8)	52 (10.4)
	Disagree	5 (10)	10 (10)	5 (5)	27 (10.8)	47 (9.4)
Reporting of ADR would help patient safety in the long term	Agree	46 (92)	92 (92)	93 (93)	232 (92.8)	463 (92.6)
	Neutral	3 (6)	0	2 (2)	5 (2)	10 (2)
	Disagree	1 (2)	8 (8)	5 (5)	13 (5.2)	27 (5.4)
Health-care providers should be taught about pharmacovigilance activities during their training	Agree	46 (82)	97 (97)	93 (93)	238 (95.2)	474 (94.8)
	Neutral	3 (6)	2 (2)	2 (2)	3 (1.2)	10 (2)
	Disagree	1 (2)	I (I)	5 (5)	9 (3.6)	16 (3.2)
Many ADRs are avoidable	Agree	29 (58)	57 (57)	63 (63)	202 (80.8)	351 (70.2)
	Neutral	9 (18)	9 (9)	12 (12)	28 (11.2)	58 (11.6)
	Disagree	12 (24)	34 (34)	25 (25)	20 (8)	91 (18.2)
Only serious or unexpected ADR need to be reported	Agree	31 (62)	27 (27)	31 (31)	71 (28.4)	160 (32)
	Neutral	5 (10)	3 (3)	7 (7)	28 (11.2)	43 (8.6)
	Disagree	14 (28)	70 (70)	62 (62)	151 (60.4)	297 (59.4)
Educational intervention may improve the culture of repotting ADRs	Agree	49 (98)	95 (95)	89 (89)	229 (91.6)	462 (92.4)
	Neutral	0	0	4 (4)	8 (3.2)	12 (2.4)
	Disagree	1 (2)	5 (5)	7 (7)	13 (5.2)	26 (5.2)

ADRs: Adverse drug reactions

Table 3: Practice of pharmacovigilance followed by health-care providers

Questions	Response in affirmative *n* (%)				
	Pharmacist	Nurses	Doctor	Students	Total
Have come across any ADR	8 (16)	40 (40)	44 (44)	152 (60.8)	244 (48.8)
Reported any ADR to the ADR monitoring center	5 (10)	27 (27)	35 (35)	161 (64.4)	228 (45.6)
Have come across "drug alerts"	12 (24)	46 (46)	44 (44)	51 (20.4)	153 (30.6)
Follow approaches to prevent ADR	16 (32)	72 (72)	62 (62)	148 (59.2)	298 (59.6)
Received training on reporting of ADRs during MBBS, postgraduate, nursing or pharmacy course	8 (16)	45 (45)	47 (47)	202 (80.8)	302 (60.4)
Maintain records of ADRs	6 (12)	34 (34)	39 (39)	141 (56.4)	220 (44)

ADRs: Adverse drug reactions

patients, and therefore the people, is that the initiative within the process.

The present study was a questionnaire-based study, including health-care providers of a tertiary care teaching hospital in VIMS, Ballari. ADR monitoring is functioning toward increasing awareness and training programs among the health-care providers, medical students, and patients it is also trying to make a culture of reporting ADRs. It has been felt that the results of the study would help the AMC in identifying areas that require to be addressed.

The study showed that the health-care providers, namely, doctors, nurses, pharmacists, and medical students,

had knowledge and a supportive attitude toward pharmacovigilance. However, the particular practice of reporting was low among the participants. Similar observations are reported by other studies from India that the prescribers have knowledge, but poor practice for reporting ADRs.[7,8]

A section of the health-care providers was not aware of pharmacovigilance and a few thought that pharmacovigilance includes drug-related problems in just the allopathic system of drugs. Although this is often lesser than other studies, it is a neighborhood that must be addressed.[8-10] There are other systems of medicines in India that use medicines from other sources such as herbs, animal products, and minerals. These are perceived as being natural products and, hence, safe. The doctors often do not take a history from patients about the use of medicines from other systems. The program involves monitoring of ADRs of all medicines (from all systems of medicines), vaccines, blood products, and even medical devices. It is essential to form the health-care providers aware of the very fact that any system of drugs, even medical devices and vaccines can cause ADRs and thus should be reported. The study revealed that although many (74.6%) professionals realize the pharmacovigilance program Programmed by the Government of India, less known about the organization liable for this and therefore the world organization (World Health Organization − Uppsala Monitoring Centre) monitoring an equivalent. Lack of awareness about this is often not drag because it will not influence reporting of ADRs by health-care providers or the standard of the pharmacovigilance program within the institution.

An important finding of the study was that, although a majority of health-care providers knew about the existence of ADR reporting system within the institution, only a few knew about the modalities available for doing it. This needs rectification, and there is a requirement to get awareness regarding the facilities available for reporting ADRs, the designated officer for pharmacovigilance activities and various sources of data available within the campus to facilitate ADR reporting.

This study also revealed that the essential knowledge of pharmacists regarding pharmacovigilance was lesser than the opposite health-care providers altogether areas. This is often almost like observation in another study from South India.[11] Pharmacists are key stakeholders involved in procurement, storage, dispensing, and disposal of medicines they need an important role within the safe use of medicines. Thus, the concept of pharmacovigilance for patient safety must be emphasized during their professional training, and continued medical education schemes should be organized regularly to update their knowledge.

An encouraging finding of this study was that the bulk of participants (>90%) considered that ADR reporting is vital and will be made mandatory. It should be taught during their training. Moreover, about 80% of participants thought that ADR reporting is their professional obligation, which is more within the studies wiped out Nagpur and Tamil Nadu[9,12] a study from India showed that 64% of health-care providers are reporting ADRs.[13] During this study, despite having an honest attitude toward reporting ADRs, only 45% of health-care providers had ever reported ADRs. Furthermore, 32% of participants want to report only serious ADRs which is lesser than the share observed in another study[8] there is a requirement to stress to the health-care providers that each one adverse reaction must be reported whether mild or serious.

Among the explanations given for not reporting, ADRs during this study were difficulty choose if an ADR had occurred or it had been a disease symptom, lack of your time, the ADR is documented and mild, and legal issues. Similar reasons have also been acknowledged in other studies.[9-11] Lack of data of where and the way ADRs should be reported would automatically affect reporting, which could even be a reason for fewer reporting of ADRs stated during this study, during which only 27% of participants have knowledge about the facilities available to report ADRs within the institution. Another issue might be that only 16–47% pharmacists, nurses, and doctors stated that that they had received training on the way to report an ADR. These findings suggest that there's a requirement for more interventions, continuous medical education, and workshops to enhance awareness about the pharmacovigilance program and therefore the various facilities available for ADR monitoring within the institution.

Another finding of concern within the study was that doctors did not agree that doctors and paramedics got to report. This is often contradictory to the opinion of the bulk of doctors that the reporting of ADR may be a professional obligation. Thus, efforts to extend awareness about the role of all involved within the use of medicines for reporting ADRs has got to be done.

Medical students were more aware of pharmacovigilance, and their attitude indicates their understanding of its importance. This is often because the department of pharmacology is sensitizing medical students about pharmacovigilance, its importance, and the way to report ADRs. It is hoped that early training will help in laying a foundation for ideas about pharmacovigilance, the very fact that medicines can cause adverse effects which may affect patient safety. As they graduate and begin practicing medicine, they are going to be ready to use medicines judiciously with more awareness about patient safety. The culture of reporting ADRs has got to be inculcated from the start of their clinical training so that it becomes a neighborhood of their practice afterward.

CONCLUSION

A positive attitude toward pharmacovigilance exists among the health-care providers and students of the institution. More

continuous medical education schemes got to be conducted to teach all health-care providers about the importance of a pharmacovigilance program, the role of all health-care providers in ensuring its success and therefore the various facilities available within the institution for reporting ADRs. The necessity for an efficient pharmacovigilance program has been realized to make sure safe use of medicines. Its success will depend on the involvement of all stakeholders within the use of medicines.

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