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Research Article

KNOWLEDGE, ATTITUDE, AND PRACTICE TOWARD PHARMACOVIGILANCE AND ADVERSE DRUG REACTION REPORTING AMONG NURSING STAFF AND STUDENTS

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ABSTRACT

Objective: The objective of this study is to assess awareness of Pharmacovigilance among the healthcare professionals and to evaluate the impact of an educational intervention for improving awareness of Pharmacovigilance among the nursing staff and nursing students from Bengaluru, Karnataka, India.

Methods: A cross-sectional study was carried out using a validated questionnaire that included demographic details and 20 survey items to evaluate the participants' knowledge, attitude, and perception (KAP) on adverse drug reactions (ADRs) and Pharmacovigilance. All participants received an interactive educational intervention in the form of a lecture. A pre- and post-KAP questionnaire survey was used to evaluate the impact of educational intervention among the participants. The Statistical Package for Social Sciences statistical software, version 16, was used to analyze the data.

Results: A total of 103 healthcare professionals in the study responded to the pre- and post-KAP survey questionnaires. 66 nursing students and 37 nursing staff were involved in the study. The increased awareness among the study subjects about pharmacovigilance between pre- and post-intervention was statistically significant ($p<0.001$) which showed the effectiveness of educational intervention carried out.

Conclusion: The results show that participants in the study were only moderately aware of ADR monitoring. However, they had expressed a positive attitude toward Pharmacovigilance and ADRs reporting. There is a need to create awareness among the nursing fraternity about ADR reporting for improving the spontaneous reporting.

Keywords: Pharmacovigilance, Knowledge, Attitude, and perception questionnaire, Adverse drug reactions.

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INTRODUCTION

The two major concerns of a drug are safety and efficacy. The efficacy of a drug can be quantified with relative ease; the same cannot be said about safety. This is because the adverse effect of a drug may be uncommon (very serious) and many patients may be affected or subjected to a potential risk before the relationship with the drug is established [1,2]. The World Health Organization (WHO) has defined adverse drug reaction (ADR) as "a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function"[3]. One of the important causes of morbidity and mortality worldwide is ADRs. Estimates suggest that ADRs are the fourth major cause of death in the United States recently [4]. The major key role in Pharmacovigilance programs is played by healthcare professionals such as physicians, pharmacist, and nurses [5,6], but with an estimated median underreporting rate (defined as the percentage of ADRs detected from intensive data collection that was not reported to relevant spontaneous reporting systems) of 94%, it is noted that underreporting is very common [7], and occurs frequently for serious and unlabeled reactions [8,9]. The detection of important ADRs is delayed due to this. According to the studies from various settings, the inadequate knowledge and attitude of healthcare professionals about Pharmacovigilance are associated with a high degree of underreporting [10-15]. It is estimated that only 6–10% of all ADRs are reported [16,17].

The word "Pharmacovigilance " is as follows: Pharmakon (Greek word for "drug") and vigilare (Latin word for "to keep watch") [18]. It is a growing discipline because of the rise of ADRs [19,20] that ensure patient care and safety using the medicines in the best way for the treatment or prevention of ADRs [21]. Pharmacovigilance is defined by the WHO as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problem, particularly long-term and short-term adverse effects of medicines" [22]. Due to the difference in drug response among individuals, various prescribing habits, drug regulatory system, and availability of drugs, it has been recommended for every country to set up their own Pharmacovigilance programs [23]. The common problem faced in Pharmacovigilance program is underreporting of ADRs [24,25]. Inadequate funds, lack of trained staff, and lack of awareness about detection, communication, and spontaneous monitoring of ADRs may be the reason, gross underreporting of ADRs is a cause of concern [7,8]. The success and effectiveness of any Pharmacovigilance system highly depend on the participation of all health care professionals, and thus, physicians, pharmacists, and nurses are also important healthcare professionals responsible for Pharmacovigilance activities and ADR reporting during their practice.

In India, Pharmacovigilance is still in early stage and there exists very limited knowledge about this discipline. Like most of the Pharmacovigilance programs around the world, even the Pharmacovigilance Program of India (PvPI) suffers from underreporting of ADRs by the healthcare professionals which leads in detecting important ADRs [26]. ADR monitoring centers (AMCs) in India are being set up across the country under PvPI reinitiated in 2010. This whole program is under the Central Drugs Standard Control

Organization, Ministry of Health and Family Welfare, Government of India [27]. As per PvPI, it is mandatory for every teaching hospital to have a Pharmacovigilance center/cell. Therefore, this study was conducted among healthcare professionals to assess their awareness on Pharmacovigilance and to evaluate the impact of an educational intervention for creating awareness on Pharmacovigilance among nursing staff and student's in Bengaluru, Karnataka, India.

METHODS

Study design and site

A questionnaire survey was conducted in two tertiary care hospitals in Bengaluru, Karnataka, India.

Source of data

The required information for the study was obtained from nursing professionals and students of study site.

Sample size

This study involved 127 participants, of which only 103 (37 nursing staff and 66 nursing students) returned the filled pre- and post-questionnaire.

Design of questionnaire

Questionnaire containing 20 questions was given to all the participants. The questionnaire was designed in such a way to assess the demographic details of the participants and had three sections containing 11 knowledge-based, 5 attitudes-based, and 4 practice-related questions, respectively.

Collection of data

The pre-knowledge, attitude, and perception (KAP) questionnaire was initially administered to all 127 participants, and the purpose of the study was explained. A theoretical presentation on what is Pharmacovigilance, PvPI, ADRs (i.e., in terms of definition, causality assessment, and seriousness), role of nursing staff in reporting, importance of reporting the ADRs, and its effect on patient safety and various tools to report ADR (i.e., forms and mobile app) was used in the educational intervention. Following the educational intervention program on Pharmacovigilance conducted by the Pharmacovigilance associates of ADR monitoring center, all participants in the study were given post-KAP questionnaire and their responses were documented. A total of 5 intervention programs were conducted to cover the study population.

Data analysis and statistics

The scores of pre- and post-test questionaries' were analyzed to study the effectiveness of educational intervention among the participants. The pre-KAP questionnaire was analyzed question wise, and their percentage value was calculated. The Statistical Package for Social Sciences statistical software, version 16, was used to analyze the data.

Validation of questionnaire

The questionnaire was a 20 item inventory titled "The standard KAP questionnaire" which was validated at one of the site. It contained 20 items that were adapted from the previous studies and literature.

RESULTS

The present study involved 103 (81.1%) participants from 127, who participated and responded.

Categorization on the demographic details of the participants involved in the study was done based on gender distribution, professional status, and experience. The thoroughly analyzed results are reported in Tables 1 and 2.

The KAP of the participants toward Pharmacovigilance and ADR reporting was evaluated by comparing the pre- and post-KAP percentage of responses. Table 3 contains a comparison of the values and percentage of positive and negative responses for the pre- and post-KAP questionnaire, respectively.

Table 1: Participant's demographic details

Designation	Gender distribution		Total number of participants n=103 (%)
	Male (%)	Female (%)	
B.Sc. nursing students	4 (6.06)	62 (93.94)	66 (64.07)
Nursing staff	8 (21.62)	29 (78.38)	37 (35.93)
Total	12 (11.66)	91 (88.34)	103

Table 2: Experience of the participants

<10 years	82
More than 10 years	21

The results of Q No-6,19 & 20 are given in graphical representation as the participants were allowed to choose multiple answers.

Fig. 1 gives a detailed overview of the responses for the knowledge-based question No 6. Participants were allowed to choose more than one option. The respondents' knowledge toward reporting of ADRs based on the seriousness indicates that they preferred to report serious and life-threatening cases 41.74% in the pre-questionnaire, which eventually changed in the post-questionnaire outcome, suggest that all ADRs must be reported irrespective of seriousness 87.37%.

The participants reason cited for not reporting ADRs and practice-based Q-19 are listed in Fig. 2. Lack of knowledge (48.54%) and whom to report (28.15%) the ADR, difficulty to pinpoint suspected drug (34.95%), and busy schedule (32.03%) were the main reasons cited before the educational intervention.

Methods preferred for ADR reporting practice-based Q 20 are depicted in Fig. 3. Opinion on their preferred mode of reporting was sought from the respondents. Most preferred was direct contact 60.19% pre-KAP. Post-KAP results show interest in reporting through Android application 32.03% and Email 27.18%.

DISCUSSION

It is not possible to prevent every ADR, but the knowledge of nursing staff in this field is very effective to decrease the rate of occurrence of ADRs [28]. It is important for the nursing staff to participate in spontaneous reporting scheme because they spend more time in the wards and it is most likely that any acute ADR will first be observed by them. In countries where nurses are already participating in the ADR reporting scheme, studies have shown that they indeed contribute positively toward the promotion of ADR reporting [29,30]. Shalini and Mohan [31] and Arjun *et al.* [32] studies have suggested that the percentage of awareness among the dental and nursing staff was surprisingly negligible and increasing awareness in nursing students and nursing staff can increase the number of ADR reports. In our study, one focus of educational intervention was to increase awareness in nursing professionals on Pharmacovigilance and PvPI, as they can play an important role in making the Pharmacovigilance program more efficacious since their work nature involves close contact with the patients for a longer duration [33]. The increase in the positive response in pre- and post-KAP questions (1–20) of the standard KAP questionnaire was clearly evident. The participants' response on question 01 and 02 were 49.51%–80.58% after the intervention and 16.50%–74.75% after the intervention, respectively.

Fig. 1 shows a positive response to educational intervention suggesting that 87.73% post-KAP response on reporting all ADRs. The percentage of overall respondents who realized the importance of ADR reporting increased from 70% to 97% from pre intervention to post intervention.

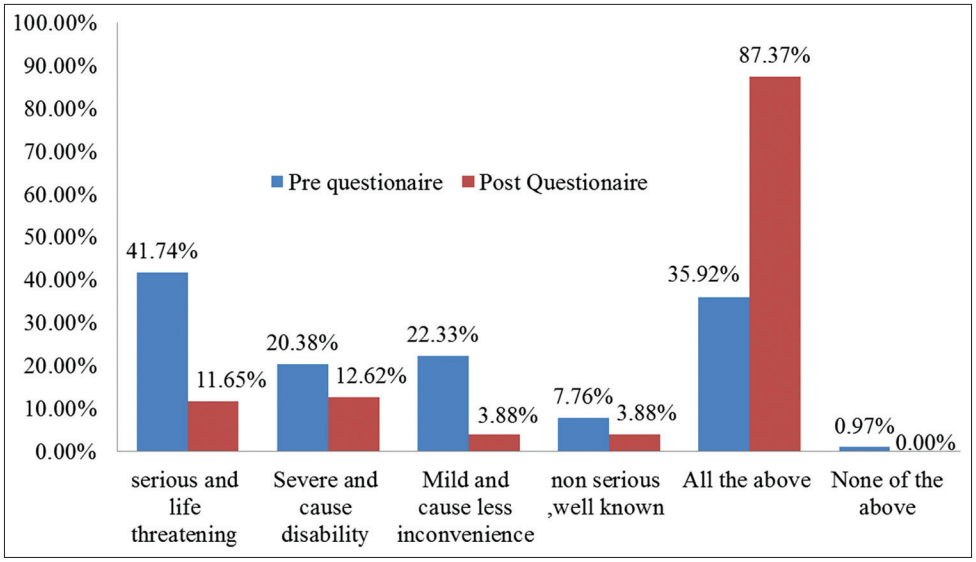

Fig. 1: Adverse drug reactions should be reported only when they are?

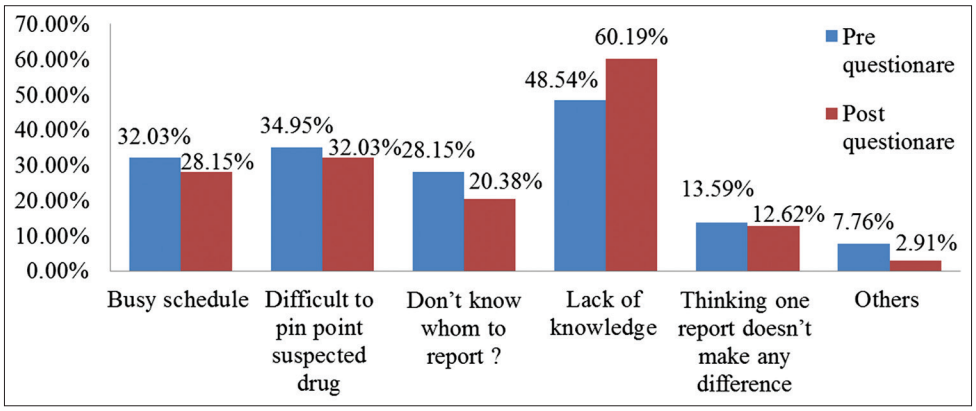

Fig. 2: Factors responsible for underreporting of adverse drug reaction's

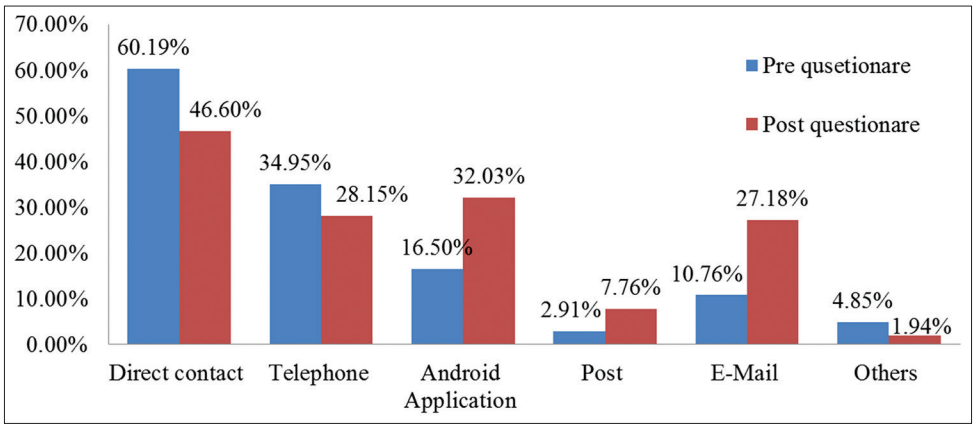

Fig. 3: Methods preferred to report adverse drug reactions

This shows that the educational intervention was well received by the participants. Question No -8 shows that 56% of staff and 24 % of students answered yes in pre-KAP to 91% of staff and 89% of student post-KAP. Kamtane and Jayawardhani also shows that a significant number of the respondents were not aware of the existence of a national Pharmacovigilance center in India [34]. The lack of awareness of participants about the existence of the PvPI and ADR reporting system (Table 3) is reflected in the result, which would ultimately affect the reporting. Therefore, personal communication and advertisement appear necessary to enhance reporting and create awareness about Pharmacovigilance program and AMC's. Question 9 shows statistically significance at $p<0.001$; The knowledge about the existence of nearby AMC found increased from 26.21% at prior to intervention to 73.78% post intervention. As per Gupta *et.al* [35] study, many healthcare professionals (75.51%) accepted that reporting ADR and teaching healthcare professionals on Pharmacovigilance are necessary. The

Table 3: Pre- and post-KAP evaluation

Q No	KAP	Pre-KAP responses (%)	Post-KAP responses (%)	p value
1	Are you familiar with the term Pharmacovigilance?			<0.0001
	Yes	51 (49.51)	83 (80.58)	
	No	52 (50.49)	20 (19.41)	
2	Pharmacovigilance is the study that relates to:			
	Safe, effective, appropriate, and economic use of medicines	6 (5.82)	3 (2.91)	<0.0001
	Therapeutic drug monitoring	3 (2.91)	0	
	Detection, assessment, understanding, and prevention of adverse effectsW	17 (16.50)	77 (74.75)	
	All the above	77 (74.75)	23 (22.33)	
3	Do you believe all the drugs available in the market are safe?			0.0449
	Yes	8 (7.76)	13 (12.62)	
	No	95 (92.24)	90 (87.38)	
4	Do you think ADR reporting is important?			
	Yes	72 (69.90)	100 (97.05)	0.0282
	No	31 (30.10)	3 (2.92)	
5	Should ADRs be reported only by physicians?			
	Yes	84 (81.55)	60 (58.25)	0.0282
	No	19 (18.45)	43 (41.74)	
7	Are you aware of any drug that has been banned due to ADR?			
	Yes	22 (21.35)	89 (86.40)	<0.0001
	No	81 (78.64)	14 (13.60)	
8	Are you aware of Pharmacovigilance Program of Indian Pharmacopeia commission, Ministry of Health, Government of India?			
	Yes	37 (35.92)	93 (90.29)	<0.0001
	No	66 (64.08)	10 (9.71)	
9	Is there any nearby ADR reporting and monitoring center in your knowledge?			
	Yes	27 (26.21)	76 (73.78)	<0.0001
	No	76 (73.78)	27 (26.21)	
10	Are you aware of PvPI android application?			
	Yes	7 (6.79)	82 (80.58)	<0.0001
	No	96 (93.21)	20 (19.42)	
11	Are you aware of PvPI toll-free number?			
	Yes	9 (8.73)	83 (80.58)	<0.0001
	No	94 (91.27)	20 (19.42)	
12	Do you think reporting ADR is necessary?			
	Yes	79 (76.69)	101 (98.10)	<0.0001
	No	24 (23.31)	2 (1.90)	
13	Do you think reporting ADR will increase patient safety?			
	Yes	76 (73.78)	99 (96.11)	<0.0001
	No	27 (26.21)	4 (3.89)	
14	Do you worry about legal problems while you think of ADR reporting?			
	Yes	62 (60.19)	24 (23.30)	0.0190
	No	41 (39.81)	79 (76.70)	
15	What is your opinion about establishing ADR monitoring center in every hospital?			
	Should be in every hospital	70 (67.96)	98 (95.14)	<0.0001
	Not necessary in every hospital	6 (5.82)	0	
	One in a city is sufficient	4 (3.88)	2 (1.94)	
	Depends on number of bed size in the hospitals	23 (22.34)	3 (2.92)	
16	Do you think Pharmacovigilance should be taught in detail to healthcare professionals?			
	Yes	73 (70.87)	98 (95.14)	<0.0001
	No	30 (29.12)	5 (4.86)	
17	Have you reported any ADR so far?			
	Yes	21 (20.38)	50 (48.54)	<0.0001
	No	82 (79.62)	53 (51.46)	
18	Have you ever counseled the patient regarding ADRs?			
	Yes	26 (25.24)	61 (59.22)	<0.0001
	No	76 (73.76)	41 (39.78)	

ADRs: Adverse drug reactions, PvPI: Pharmacovigilance Program of India, KAP: Knowledge, attitude, and perception

positive response rate of 76.69% before to 98.10% and 73.78% before to 96.11% after the educational intervention program, respectively, for question 12 and 13 indicates that participants felt that ADR reporting is necessary and thinks that it will increase patient safety. However, question 14 shows that legal fear for reporting needs to be changed. Nursing staff should accept ADR reporting as a professional obligation and overcome the fear. To remove misconceptions and modify, the attitude of nurses toward reporting personal discussions and awareness programs will be more helpful.

Question 15 shows that 95.14% of participants felt ADR monitoring center should be present in every hospital after the educational

intervention. Question 16 shows that 70.87% pre-KAP to 95.14% post-KAP results suggest that all healthcare professionals should be educated in depth about Pharmacovigilance program. From our study, it has been noticed that a maximum number of participants are having a positive attitude toward Pharmacovigilance program which is a welcome sign toward PvPI. The actual reporting was very low, even when ADR reporting was considered to be important by a majority of the respondents. Previous studies also establish that underreporting of ADRs is a worldwide phenomenon [7,11,35,36]. While it is important to note that these studies were carried out among physicians, several other studies involving nurses have indeed confirmed that underreporting of ADRs is common to all healthcare professionals [31,32]. To improve the ADR reporting, there is a direct need of knowing the reasons for underreporting [37].

Fig. 2 shows the reasons for underreporting in our study, which was lack of knowledge, difficulty to pinpoint suspect drugs, and busy schedule. This was supported by the study conducted by Chatterjee *et al.* [38], which stated that the clinical negligibility of the adverse reaction due to lack of time and little knowledge about the types of reactions to be preferentially reported are the main reason for underreporting of ADRs. Fig. 3 shows the methods preferred for ADR reporting in which the results of pre-KAP show the lack of awareness in the participants about the existence of various reporting tools.

The post-KAP results reflect positive response toward using information technology in ADR reporting. The overall study findings suggest the need for periodic awareness programs for the healthcare professionals regarding the ADR monitoring program in the hospital and the ADR reporting procedure. This might encourage the healthcare professionals to actively participate in the ADR reporting.

CONCLUSION

The influence on ADR reporting strongly lies on the knowledge and attitudes. The lack of knowledge and negative perceptions about Pharmacovigilance and ADR reporting would lead to ADR underreporting. To resolve the deficits in the practice of ADR reporting among nursing staff, it is necessary to create awareness on the importance of reporting, the reporting system, and their obligation to report ADRs. Majority of respondents agreed that reporting of ADR and teaching healthcare professionals in detail about Pharmacovigilance are necessary. Further, our study strongly suggested that healthcare professionals, especially nursing staff, should be trained on ADR reporting since they are in closer association with patients.

LIMITATION

The present study was done only on nursing professionals from two hospitals. There is a scope for the study in larger group of nursing professional.

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AUTHORS CONTRIBUTION

Dharini and Nagarjuna reddy collected data and Pramod kumar and Deepalakshmi helped in statistics.

CONFLICTS OF INTEREST

None declared

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