

ASSESSMENT OF EDUCATIONAL INTERVENTION ON KNOWLEDGE, ATTITUDE, AND PRACTICES OF RURAL COMMUNITY PHARMACISTS OF MYSURU DISTRICT TOWARD ADVERSE DRUG REACTION REPORTING

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ABSTRACT

Objective: A prospective interventional study was conducted to evaluate the impact of educational intervention on knowledge, attitude, and practices (KAP) of rural community pharmacists toward adverse drug reaction (ADR) reporting.

Methods: A validated KAP questionnaire was administered on the enrolled community pharmacists in the study. SPSS software package version-19 was used to calculate the influence of educational intervention on KAP scores of the participants. Pre-training KAP scores were compared with the post-training KAP scores.

Results: About 49 community pharmacists have participated in the study, 95.91% (n=47) were males, and 4.08% (n=2) were females. The mean±SD age of the participants was 40.93±7.84 years. The mean ± SD score in the knowledge component was significantly increased from 4.87±2.015 to 7.09 ± 0.68 (n=49, p<0.05). After the educational intervention, 77.55% (n=38) of participants could correctly define the ADRs, and 73.46% (n=36) of participants were aware of the consequence of ADRs. About 57.34% of participants disagree with the statement reporting of ADRs incurs the additional workload with post education intervention. At the end of the study, the participants' knowledge was significantly increased and participant pharmacists felt responsible toward ADR reporting.

Conclusion: Educational interventional program have shown a tremendous change in knowledge and awareness of the respondents towards adverse drug reaction monitoring and reporting. It is well understood that there is a need for promoting the pharmacovigilance activities among community pharmacists.

Keywords: Community pharmacist, Adverse drug reactions reporting, Educational intervention.

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INTRODUCTION

Adverse drug reactions (ADR) are identified as one of the major contributing factors for morbidity and mortality [1]. Global studies have corroborated ADRs as fourth to, sixth leading cause of death in hospitalized patients [2] and also have a direct influence on morbidity, mortality, and economic burden to the society [3]. The global epidemiological data show that 3–6% of hospital admissions are due to ADRs and the percentage of patients experiencing ADRs during hospitalization ranges from 1.5% to 35% [4]. As per a South Indian-based study, the estimated direct and indirect cost associated with the management of an ADR is about Rs.4945/- per day [5]. Findings from overseas studies reveal that the expenditure incurred in managing ADRs is ranging from few million dollars at the institutional level to billions of dollars at the national level [5]. Thus, ADRs are a significant burden to health-care systems around the world in terms of the resource consumption [1-5]. Studies have also shown that the incidence of ADRs in community settings is estimated at a rate of 57% and often goes undetected majorly due to underreporting by health-care professionals [6]. Spontaneous ADR reporting systems function worldwide to collect information on ADRs to identify early signals of drug toxicity and ultimately prevent drug-associated harm. Pharmacovigilance programs of various countries have already permitted pharmacists to report ADRs in their practice settings [6]. Despite many efforts, underreporting of ADRs still is a challenge [7]. Underreporting of ADRs by community pharmacists is due to poor understanding about the concept of ADR reporting [3-7].

Community pharmacists are easily accessible to public for any health-related issues. In recent times, pharmacists' roles were

expanded from traditional dispensing to patient care services through pharmaceutical care [8]. Community pharmacists can play a vital role in the pharmacovigilance program because of their rapport with the patients [9]. Research studies have acknowledged community pharmacists' role in recognizing and reporting the ADRs to their national pharmacovigilance programs. A systematic review of ADR reporting schemes of various countries shows that quality of ADR reporting by pharmacists is on par with other health-care professionals. In India, community pharmacists' awareness and ADR reporting practice are very low. A study was conducted in Amalapuram by Sindhuja *et al.* to assess the knowledge, attitude, and practices (KAP) of community pharmacists toward ADR reporting. The findings suggest that community pharmacists in India do not have understanding about the ADR reporting [10]. Pilot study findings of Rakesh and Adepu in Mysuru city suggest that if pharmacists are given adequate training, they will take the responsibility of reporting ADRs [11]. Thus, this prospective interventional study was designed to assess the impact of educational intervention on community pharmacists' KAP toward ADR reporting.

METHODS

The present study was conducted involving the practicing community pharmacists of rural areas of Mysuru district, South India. Postal survey and convenient sampling methods were applied to recruit the practicing pharmacists in the study. A 20-item questionnaire was developed comprising of 8 questions assessing "knowledge" component, 6 questions assessing "attitude" component, and another 6 questions to assess "practice" component, and the questionnaire was validated with the help of clinical pharmacy professors and practicing community

pharmacists. Both pre- and post-training questionnaire were having the same set of questions. In the questionnaire, provision was also made to capture the participants' demographic details such as name, age, sex, and educational*background and practice experience. Baseline knowledge of the participating community pharmacists was assessed by applying the questionnaire before the educational program. Impact of the educational intervention on KAP was assessed by administering the same questionnaire after 4 weeks on the study pharmacists. The Institutional Ethics Committee of JSS College of Pharmacy, Mysuru, has approved the study.

A training manual*was developed by*referring to the textbooks and published literature on ADRs and pharmacovigilance. The manual covered the information on definition, pre-disposing factors, various methods practiced to report ADRs, spontaneous reporting, global scenario of pharmacovigilance, what information should be collected from patients to report ADR, the ADR notification form, and procedure to fill the form. The content of the manual was reviewed by the senior faculty of the pharmacy practice and experts in pharmacovigilance activity.

A workshop on ADR detection, reporting, and monitoring was organized for selected rural practicing community pharmacists. During the workshop, the participants were trained about the topics covering basic introduction on ADRs, need for safety monitoring of medicines in the society, role of pharmacists in drug safety monitoring and global scenario of ADR reporting, and how to initiate and improve ADRs reporting culture among community pharmacists.

Validation of the KAP questionnaire

The KAP questionnaire was subjected for the content validity index (CVI) with the help of four-point criteria for measuring the CVI. Each question in the questionnaire was subjected for the content validity by fifteen experts in the related field. The experts were from the professors, lectures, research scholars, and pharm.D interns of the department of pharmacy practice. The researcher gave a copy of the questionnaire with the criteria for CVI and explained the purpose and the objective of the study individually to all experts. The experts were asked to rate each question and answer options on relevance, clarity, simplicity, and ambiguity on the four-point scale. The CVI of the scale was also measured based on the rating by the experts. The statistical analysis was performed using Microsoft Excel and the Statistical Package for the Social Science (SPSS) version 22 for windows. Cronbach's alpha was used to estimate the internal consistency of the questions in the questionnaire.

RESULTS AND DISCUSSION

The content validation of the KAP questionnaire was done and the internal consistency is presented in Table 1.

About 49 practicing pharmacists participated from six taluks of mysuru district

Among 49 community pharmacists, 95.91% (n=47) were male. The mean age of the pharmacists was 42.69±7.65 years. The sociodemographic details of the study pharmacists are presented in Table 2.

The enrolled rural community pharmacists have completed pre- and post-training KAP questionnaire. The knowledge of community pharmacists toward ADR reporting and monitoring was assessed through 8 questions. The community pharmacists' overall pre- and post-test responses were compared based on the number of questions answered correctly, and the results were analyzed using Chi-square test in SPSS statistical software. The post educational knowledge score of participants was significantly increased from 4.87±2.01 to 7.09±0.68 (n=49, p<0.001). Question 1 was framed to assess the knowledge of the respondents about the definition of ADR, on post-training, 77.55% (n=38) of pharmacist respondents have given the correct response for this question, and a significant improvement between pre- and post-

Table 1: Internal consistency of the KAP questionnaire

Criteria	Cronbach's alpha
Clarity	0.782
Relevancy	0.824
Simplicity	0.814
Consistency	0.728

KAP: Knowledge, attitude, and practices

Table 2: Sociodemographic details of the participant pharmacists

Characteristics	Frequency (%)
Gender	
Male	47 (95.91)
Female	0.2 (4.08)
Age in years	
25-29	02 (4.08)
30-34	10 (20.70)
35-39	09 (18.36)
40-44	16 (32.65)
>45	12 (24.48)
Community pharmacists' qualification	
D. Pharm	44 (89.79)
B. Pharm	05 (10.20)
Number of years of experience as community pharmacists	
<5	06 (12.24)
6-10	07 (14.28)
11-15	15 (30.61)
>15	21 (42.85)
Number of prescription dispensed per day	
<30	21 (42.85)
30-90	17 (34.69)
>90	11 (22.44)
Use of computer for billing	
Yes	12 (24.48)
No	37 (75.51)
Access to internet in pharmacy	
Yes	11 (22.44)
No	38 (77.55)

KAP scores was observed. Question number 2 assessed the predisposing factors for developing an ADR. The results have shown that 63.26% (n=31) of the pharmacists' respondents have given the correct answer in post-KAP, whereas in pre-KAP, the response was 42.85% (n=21). The response rate is statistically significant between pre- and post-KAP. The question number 3 focused on the types of ADRs. About 52.38% (n=22) of participants gave the correct response when compared with pre-KAP assessment. Response rate for question 3 was statistically significant between pre- and post-KAP scores (p<0.05). Question 4 assessed about the knowledge on consequence and economic burden of ADR on the patients. The response rate for question 4 in post-KAP was found statistically significant (p<0.05). Questions 6 assessed about the awareness on existing national pharmacovigilance program in India. The result has shown that 83.67% (n=41) of participants were aware about existing Pharmacovigilance Program of India (PvPI). After the educational intervention, post-KAP response in this question significantly improved (p<0.05). Question number 7 sought information about agency that is responsible for ADR monitoring in India. Response rate for question 7 was significantly improved in post-KAP test. About 63.26% (n=31) of participants were given the correct response (p<0.001). Question number 8 asked about which health-care professionals are permitted to report ADRs. To this question, 16 (32.65%) participants have correctly answered in pre-training KAP test, whereas 41 (83.67%) participants have correctly answered in the post-training test showing a significant improvement in answering. The scores associated with knowledge component is presented in Table 3.

While evaluating the attitudes of community pharmacists, it was observed that 42.85% (n=21) of participants have strongly agreed with the statement of "ADR reporting is the professional responsibility of pharmacists" a statistically non-significant difference was observed in pre- and post-KAP scores ($p>0.05$). In pre-KAP response, the majority of the participants (n=36) have mentioned that reporting ADR will add additional workload to pharmacists. After the educational intervention, 51.01% (n=25) participants have expressed disagree with above-said statement which is significantly different between pre-KAP and post-KAP. At the end of the educational intervention, majority participants 87.76% (n=43) have agreed with the statement "for reporting ADRs need special knowledge" comparing to the pre-training KAP. No statistically significant difference was observed between pre-training and post-training KAP assessment ($p>0.05$). After the educational intervention, 38.77% (n=19) of the participants have expressed their disagreement with the statement "doctor will have a negative opinion on pharmacists reporting any ADR" comparing to the pre-training scores. A statistically significant difference was observed between the responses to this question in pre- and post-KAP assessment ($p<0.05$). All the participants have agreed to the statement "If I am encouraged and trained I will take the responsibility of reporting

ADRs." The scores of Attitude are presented in Table 4.

The responses to the questions in the practice session after the education intervention were as follows. About 46.93% (n=23) participants have mentioned that they frequently check the allergy status of the patients while dispensing medications to them. About 83.67% (n=41) of participants declared that they will take the responsibility of educating the patients on safe use of medicines. About 83.67% (n=41) of participants have said that they will provide counseling to their patients about potential ADRs. About 75.51% (n=37) of participants have agreed to report the ADRs to the suitable authority comparing to the pre-KAP assessment. Significant difference was observed between the responses to this question in pre- and post-intervention ($p<0.05$). The scores on practice are presented in Table 5.

This study was carried out to assess the KAP of community pharmacists toward ADR reporting. The study has also evaluated the effectiveness of the education intervention program on ADR reporting to improve the awareness* by community pharmacists in Mysuru district.

At present, in India, the minimum registrable qualification for pharmacists to practice is diploma in pharmacy (D. Pharm). Their

Table 3: Evaluation of pre- and post-training knowledge scores

Questions	Correct response before training (n=49)	Correct response after training (n=49)	p value
What is an ADR?	14 (28.57)	38 (77.55)	<0.05
Which of the following factors predispose for developing an ADR?	21 (42.85)	31 (63.26)	<0.05
Which of the following ADR classification is correct?	10 (20.40)	29 (59.18)	<0.05
Which of the following are the consequences of ADRs?	18 (36.73)	36 (73.46)	<0.05
Which of the following organ systems of the body will be affected due to an ADR?	24 (59.18)	37 (75.51)	<0.05
Are you aware of national ADR reporting system in India?	08 (16.32)	41 (83.67)	<0.05
Which of the following agency is responsible for ADR monitoring in India?	05 (10.20)	31 (63.26)	<0.05
Which of the following health-care professionals is permitted to report ADR?	16 (32.65)	41 (83.67)	<0.05

ADR: Adverse drug reaction

Table 4: Pharmacists scores on attitude toward ADR reporting

Questions	Strongly agree (%)		Agree (%)		Disagree (%)		Strongly disagree (%)		p value
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	
Do you think ADR reporting is one of the professional responsibilities of the pharmacists?	21 (42.85)	37 (75.51)	22 (44.89)	09 (18.36)	04 (8.16)	03 (6.12)	02 (4.08)	00	>0.05
Is reporting of ADRs an extra work for you	16 (32.65)	08 (16.32)	20 (40.81)	16 (32.65)	11 (22.44)	16 (32.65)	02 (4.08)	09 (18.36)	< 0.05
I need special knowledge and skills for reporting of an ADR	23 (46.93)	25 (51.02)	16 (32.65)	18 (36.73)	08 (16.32)	04 (8.16)	02 (4.08)	02 (4.08)	> 0.05
Will incentives for reporting ADR be a motivation for you?	16 (32.65)	04 (8.16)	17 (34.69)	15 (30.61)	13 (26.53)	22 (44.89)	03 (6.12)	08 (16.32)	< 0.05
You think that doctors will have a negative opinion on you if you report an ADR?	13 (26.53)	15 (30.61)	26 (53.06)	15 (30.61)	08 (16.32)	14 (28.57)	02 (4.08)	05 (10.20)	<0.05
If I am encouraged and trained, I will take the responsibility of reporting ADR	17 (34.69)	24 (48.97)	25 (51.02)	21 (42.85)	05 (10.20)	03 (6.12)	02 (4.08)	01 (2.04)	>0.05

ADR: Adverse drug reaction

Table 5: Community pharmacists practice toward ADR reporting (n=49)

Questions	Frequently (%)		Sometimes (%)		Rarely (%)		Never (%)		p value
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	
Before dispensing any drug, how often do you ask the patients about any drug allergies?	12 (24.48)	23 (46.93)	23 (46.93)	20 (40.81)	09 (18.36)	06 (12.24)	05 (10.20)	00	>0.05
How often you talk about safe use of medicines?	19 (38.77)	13 (26.53)	21 (42.85)	28 (57.14)	07 (14.28)	08 (16.32)	02 (4.08)	00	>0.05
How often you counseled about adverse effects?	09 (18.36)	15 (30.61)	27 (55.10)	26 (53.06)	08 (57.14)	07 (14.28)	05 (10.20)	01 (2.04)	>0.05
How often do you report the suspected ADR to a suitable authority	05 (10.20)	12 (24.48)	15 (30.61)	21 (42.85)	14 (28.57)	12 (24.48)	15 (30.61)	04 (8.16)	<0.05
How often you reported the ADR to Monitoring Centre	02 (4.08)	12 (24.48)	08 (16.32)	25 (51.02)	06 (12.24)	08 (16.32)	33 (67.34)	04 (8.16)	<0.05
How often you have collected the necessary information to improve the quality of reporting	00	07 (14.28)	08 (16.32)	22 (44.89)	11 (22.44)	13 (26.53)	30 (61.22)	07 (14.28)	>0.05

ADR: Adverse drug reaction

awareness toward ADRs and pharmacovigilance activity are very minimal. Reasons for this situation are due to lack of instruction about ADRs and role of the pharmacists in reporting ADRs at diploma in pharmacy course, trader attitude of the practicing pharmacists, and nonavailability of practice guidelines for the pharmacists in India.

Community pharmacy is an important point of contact for the patients where they can procure their medicines and share their problems regarding drug therapy if any with the pharmacist.

As per the World Health Organization definition, pharmacovigilance is detection, reporting, assessment, and prevention of adverse drug effects in humans. Community pharmacists are well trained to offer the pharmaceutical care to patients for safe use of medication and help patients to receive the best therapeutic benefits. As part of pharmaceutical care process, patients are motivated for potential ADRs. Worldwide, pharmacovigilance activity is becoming a priority for all health-care professionals as the drug safety is becoming paramount. Majority countries have developed their own pharmacovigilance programs and encouraging all their health-care professionals to report ADRs. In few countries, community pharmacists are playing the lead role in ADR reporting. In the Netherlands, more than 40% of ADR reports received by Lareb are from the community pharmacists indicating their dedication toward monitoring and reporting ADRs. Few studies have also assessed the quality of reporting by community pharmacists compared with that of reports received from doctors. The findings suggest that, the quality of pharmacists reporting is on par with reports received from clinicians [12].

Before the educational intervention, the majority of the participant pharmacists were not aware of existing pharmacovigilance program in India, and they did not know how to report and where to report ADRs. The study findings have demonstrated that the community pharmacists possess a positive attitude toward ADR reporting, although the majority of them never reported any ADRs. In a study conducted by Cheema *et al.* in London observed in their study "Community Pharmacist-Led New Medicines Service for patients with long-term medical condition - A cross-sectional study has revealed that ADR reporting has identified new service by community pharmacists to be offered to the patients voluntarily to identify potential ADRs that lead to increased morbidity in patients with chronic diseases not only improves patients health but also the reputation to the pharmacist [13] that similar findings were also observed in the studies conducted at United Arab Emirates and Malaysia with respect to the positive attitude of the community pharmacists in reporting ADRs in the community pharmacy settings [12,14,15].

Knowledge and skills are essential in providing meaningful and useful professional service. It is always important for all health-care professionals to have the necessary knowledge and attitude to do any professional service. Despite many efforts by the national pharmacovigilance program action committees, ADR reporting in many countries is not picking up commendably. One of the major reasons for underreporting was found as "lack of knowledge and poor attitude" toward ADR reporting among health-care professionals [14].

Thus, the current study was focused to assess pre and post educational intervention on "KAP" of participants toward ADR reporting. The findings suggest that the knowledge component score of the participants has increased from pre-training test score of 4.87 ± 2.01 to post-test score of 7.09 ± 0.68 , which is a significant improvement ($p < 0.001$) suggesting the influential role of training on exit-level knowledge of the participants. Findings of various studies regarding assessment of KAP of pharmacists toward ADR reporting suggest that pharmacists have inadequate knowledge regarding ADRs, predisposing factors and reporting of ADRs [15].

The findings of the study also recommended that if the pharmacists are sensitized and trained, they will take the responsibility of reporting ADRs. This finding was consistent with Jose *et al.* [16] study where it was opined that educational interventions have to be continued to enhance their awareness on how to report ADR and motivate the pharmacists' toward active participation in the ADR reporting program.

In this study, it was observed that inadequate awareness about the PvPI has contributed toward the underreporting of ADRs. Further, the majority of the participants in this study (69.73%) do not possess computer and internet facility at their practicing sites as their pharmacies are in rural areas. This may be another contributing factor toward underreporting.

In a pilot study conducted in Oman by Jimmy Jose *et al.*, the findings suggest that though majority respondent pharmacists have basic knowledge about ADR reporting but require continuous educational support to update their knowledge and reporting behavior [16]. In another study conducted by Elkalmi *et al.* in Malaysia, the educational intervention has significantly improved the knowledge of the respondent community pharmacists ($p < 0.001$) compared to the pre educational intervention suggesting the importance of continuous education [12]. However, according to a study conducted by Ravinadan *et al.* [17] revealed that the community pharmacists were

having low knowledge and poor attitude toward ADR reporting. On similar notes, a study conducted by Elkalmi *et al.* in Malaysia assessing the northern Malaysian states community pharmacists' attitudes, perceptions and barriers toward ADR reporting, the findings suggest that the majority of respondent community pharmacists were unaware about ADR reporting system, and only a few pharmacists have reported ADRs to national pharmacovigilance system [12].

These findings emphasize the need for regular motivation to the practicing community pharmacists toward ADR reporting. Motivational strategies include continuous educational support to the community pharmacists, wide publicity about the pharmacovigilance activities among the pharmacists through newsletters, sending thank you notes to the pharmacists whenever a report is sent to the pharmacovigilance program and publishing the photo of the pharmacists in news letter, etc.

In our study, the post education intervention responses show that majority pharmacists have considered ADR reporting as one of their professional responsibility apart from the drug dispensing. This attitude in pharmacists was changed due to educational intervention and briefing them about pharmacists role in national pharmacovigilance program. The practice licensing authorities such as state pharmacy councils or pharmaceutical associations or boards of pharmacies should take the lead in this direction to motivate the practicing pharmacists toward the medication safety assessment activity. To achieve this, pharmacy council of India has come out with Pharmacy Practice Regulations in 2015. All state pharmacy councils should implement these practice regulations, upgrade pharmacist's knowledge and skills and motivate them toward the patient care activities, including pharmacovigilance activity.

CONCLUSION

The study findings concluded that pharmacists have inadequate knowledge about ADRs, the importance of spontaneous ADR reporting system, and PvPI activities. Educational intervention has significantly improved KAP of the community pharmacists toward ADR reporting. However, there is a strong need to implement practice regulations and regulatory interventions periodically to improve the understanding of safety reporting among the practicing community pharmacists.

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AUTHOR'S CONTRIBUTION

Both authors have contributed equally for the research work in designing the research project, developing the training module

and necessary assessment questionnaires, and also in enrolling the practicing pharmacists for the proposed work.

CONFLICTS OF INTEREST

Authors have declared that there are no conflicts of interest.

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