

## IMPACT OF EDUCATIONAL INTERVENTION ON KNOWLEDGE, ATTITUDE, AND PRACTICES OF URBAN COMMUNITY PHARMACISTS TOWARD ADVERSE DRUG REACTION REPORTING IN A SOUTH INDIAN CITY

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### ABSTRACT

**Objective:** To assess the knowledge, attitude, and practices (KAP) of community pharmacists toward adverse drug reaction (ADR) reporting and also to evaluate the impact of the educational program on community pharmacist's knowledge and perception toward ADR reporting.

**Methods:** A prospective cross-sectional study was carried out by administering a validated questionnaire before and after the educational program on a sample of 26 community pharmacists. The baseline score of pre-training KAP was compared with the post-training KAP. The SPSS statistical version 19 was used to compare the difference in the KAP of the pharmacists before and after the educational program. Frequencies and percentage were used to measure demographic details of the participants.

**Results:** 26 community pharmacists have participated in the study. The mean pre-training KAP score was increased from  $4.30 \pm 2.02$  to mean post-training score of  $7.32 \pm 0.94$ . After the educational program, 92.30% (n=24) of participants were able to identify potential risk factors responsible to cause ADRs, and 80.76% (n=21) of participants were aware of the consequence of ADRs. Upon educational intervention 73.07% (n=19) of participants disagree with the statement of ADR reporting in the community pharmacies lead to additional workload and were confident about their knowledge in ADR reporting and monitoring.

**Conclusion:** The study concludes that the educational intervention has increased the KAP of the trained community pharmacists toward ADR reporting.

**Keywords:** Community pharmacists, Adverse drug reaction reporting, Educational intervention, Knowledge, Attitude and practices.

### INTRODUCTION

Drugs are used to treat illnesses by virtue of their therapeutic properties. However, at the same time, they can also produce unwanted or unpleasant effects known as adverse drug reactions (ADRs) [1,2]. Many research studies have corroborated that ADRs are rated as the fourth to sixth leading cause of death in hospitalized patients [3] and also manifest impact on morbidity, mortality, and economic burden to the society [4]. The World Health Organization (WHO) defines ADRs as an unintended and noxious response to a drug that occurs at doses normally used for the prophylaxis, diagnosis, or therapy of diseases, or for the modification of physiological function [5]. Global scenario of ADR incidence projects that 3% to 6% of the hospital admissions are due to ADRs [3], and percentage of patients' experience ADRs during hospitalization are ranging from 1.5% to 35%. An international study has estimated the incidence of ADRs in community settings as 57%, and often they go undetected due to poor reporting practices of health care providers [6].

The spontaneous reporting system is an important post-marketing surveillance method for assessing medicine safety data and practiced by various national pharmacovigilance programs. To report the suspected ADRs, many national pharmacovigilance programs permits all health care professionals including pharmacists [7]. Despite of various efforts, under-reporting of ADRs has become a major barrier in strengthening pharmacovigilance activities [8]. Poor understanding of the healthcare professionals about the importance of ADRs reporting might be one of the reasons for under-reporting [9].

Community pharmacists are the most easily accessible health care professionals to the general public in all healthcare related issues.

In recent years, pharmacists have become increasingly involved in patient care and have expanded their traditional role of preparing and dispensing medications to influencing the prescribing process and delivery of pharmaceutical care services [10]. Community pharmacists as health care professionals can also play an important role in the pharmacovigilance program due to their direct contact with the patients. Many international studies have appreciated community pharmacists' role in identifying and reporting the ADRs to their national Pharmacovigilance programs. A Netherland based study findings suggest that 40% of the ADR reports received by Lareb are contributed by the community pharmacists [11]. To improve the reporting rate, it is essential to update the knowledge, attitude, and practices (KAP) of the community pharmacists toward ADR reporting.

In 2005, the South Indian based pilot study findings revealed that adequate education to the practicing community pharmacists has improved their knowledge and motivated them toward reporting ADRs. At the end of training, 10 trained community pharmacists reported 42 ADRs in 3 months period [12]. The present study is focused to assess KAP of the community pharmacists toward ADR reporting in Mysore city and also to assess the impact of educational intervention on their knowledge and practices toward ADR monitoring and monitoring.

### METHODS

This prospective interventional study was designed to assess the impact of an education program on community pharmacists' KAP toward ADR reporting. The study was conducted in Mysore city, South India. Practicing community pharmacists were recruited in the study through a postal survey. 26 community pharmacists have consented to participate in this educational interventional program.

A 20 items questionnaire comprising 8 questions assessing "knowledge" component, 6 questions assessing "attitude" component, and another 6 questions to assess "practice" component were designed, and content validation was done with professors of clinical pharmacy. Both pre- and post-training questionnaire possessed the same set of questions.

The questionnaire also possesses questions to capture demographic details of the participants' such as name, age, sex, and educational background and practice experience of the respondents. This study includes the pre- and post-educational interventional assessment of KAP among the selected practicing community pharmacists. Baseline knowledge of the participating community pharmacists was assessed by applying the questionnaire before the educational program. The impact of the training program on improved knowledge and perception was assessed by administering the same questionnaire after 2 months on the same pharmacists.

The Institutional Ethics Committee of JSS College of Pharmacy, Mysore has granted the ethical approval for the study.

#### Conducting of the education program on ADR reporting

A training manual was developed by referring to the textbooks and published literature on ADR. The manual covers the definition, pre-disposing factors, various methods practiced to report ADRs, spontaneous reporting, international and national scenario of pharmacovigilance, information required 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.

Half-a-day workshop on ADR detection, reporting and monitoring were organized for selected practicing community pharmacists at the institution. During the workshop, topics covered were the introduction to ADRs, need for safety monitoring of medicines, how to initiate ADRs reporting culture in community pharmacies, role of community pharmacist in drug safety monitoring at community pharmacy and in ADR reporting system.

#### RESULTS

A total of 26 community pharmacists have attended the workshop. Among the 26 community pharmacists, 25 participants (96.15%) were males and only one participant was female. Among the participants, the majority of them (42.30%) belonged to the age group of 40-44 years, followed by 23.07% of participants were >45 years. Most of the participants (84.61%) were qualified with a diploma in pharmacy followed by 15.38% were with bachelor in pharmacy (B. Pharm) qualification. Practice experience of majority (46.15%) participants is more than 15 years, and the mean practice experience was 15.28±7.03 years. The majority of the participants (65.38%) did not have internet facility in their pharmacy. Complete demographic details of the participants are presented in Table 1.

#### Evaluation of participants' knowledge toward ADR reporting

A total of 26 practicing community pharmacists of Mysore city have completed the pre- and Post-training KAP questionnaire. The knowledge of community pharmacists toward ADR reporting was assessed by 8 questions in knowledge component. The pre- and post-training knowledge of the participants were compared, and results were analyzed using Chi-square test in SPSS statistical software version 19. In a post-educational intervention, the knowledge score of participants was significantly increased from 4.30±2.02 to 7.38±0.94 ( $p<0.001$ ). Question number 1 was framed to assess the knowledge of the participants about ADR definition. The response rate for this question was not significantly improved from pre-training to post-training as the majority of the participants know the answer. Question number 2 assessed the pre-disposing factors for developing an ADR. The results have shown that only 15 participants (57.69%) have correctly answered in pre-training, whereas in the post-training

Table 1: Demographics data of the participants (n=26)

Characteristics	Frequency	%
Gender		
Male	25	96.15
Female	01	03.84
Age in years		
25-29	04	15.38
30-34	02	7.69
35-39	03	11.53
40-44	11	42.30
>45	06	23.07
Qualification		
D. Pharm	22	84.61
B. Pharm	04	15.38
Practice experience in years		
<5	2	7.69
6-10	6	23.07
11-15	6	23.07
>15	12	46.15
Number of prescriptions dispensed per day		
<30	09	34.61
30-90	11	42.30
>90	06	23.07
Use of computer for billing		
Yes	11	42.30
No	15	57.69
Internet access in the pharmacy		
Yes	09	34.61
No	17	65.38

test, 24 participants (92.30%) have correctly answered showing a statistically significant improvement in answering. Question 3 sought information about types of ADRs; the results have shown that 9 (34.61%) participants have correctly answered in pre-training KAP while in the post-training test 24 (92.30%) participants have correctly answered showing a statistically significant improvement in the response. Question number 4 sought information about consequence and economic burden of ADRs to the patients. The results have shown that 10 (38.46%) participants have correctly answered in pre-training KAP and in the post-training test, 21 (80.76%) participants have correctly answered showing a statistically significant improvement in answering. Question 6 sought information about awareness about existing national ADR reporting system. The results have shown that 11 (42.30%) participants were aware of the existing national reporting program in the pre-training KAP and while in the post-training test, 22 (84.61%) participants have answered about national pharmacovigilance program, showing a statistically significant improvement in answering. Question 7 was on information about an agency which is responsible for ADR monitoring in India; the results have shown that 4 (15.38%) participants have correctly answered in pre-training and while in the post-training test, 15 (57.69%) participants have correctly answered showing a statistically significant improvement in answering. Question number 8 asked about which health care professionals are permitted to report ADRs. To this question, 19 (73.07%) participants have correctly answered in pre-training KAP, whereas 26 (100%) participants have correctly answered in the post-training test showing a significant improvement in answering. The observations are shown in Table 2.

#### Evaluation of participants' attitudes

In assessing the attitudes of the practicing community pharmacists, a set of six questions in attitude category was asked. To the question of "ADR reporting is the professional responsibilities of Pharmacists," majority participants (84.61%) have strongly agreed (SA) in the pre-test and the response rate was increased to 88.46% in the post-test suggesting a change in the attitude. To another question of "ADR reporting is an extra work for me," the response rate was significantly improved from SA (80.76%) in pre-test to disagree (57.69%) and strongly disagree (15.38%) in post-test which is statistically significant improvement.

The mixed response was seen with question "special knowledge and skills are needed for reporting an ADR." To the question "will incentive for reporting ADR be a motivation for you," the response was significant suggesting the participants have considered ADR reporting as a professional responsibility than as a mere income source. To another question "will doctors have negative opinion if you report ADRs," the post-training response was more in favor of agree (50%) compared to SA (80.76%) in post-training. To the last question in attitude component "will you take the responsibility of reporting ADR," the response from the participants is mixed from SA (96.15%) in pre-training test to 50% (SA) in post-test. All the responses with their percentages were shown in Table 3.

#### Evaluation of practices of the participants' toward ADR reporting

To assess the "Practices" of the community pharmacists toward ADR reporting, 6 questions were asked in the questionnaire. To the question "before dispensing the drug how often you ask the patients about any drug allergies," the responses was improved from pre-training test (34.61%) to post-training score of 53.84% in "frequently" response. To another question "How often you take the responsibility talking to your patients about safe use of medicines," the responses were improved from sometimes (38.46%) to frequently (57.69%) in the post-training test. To the question "How often patients are informed about ADRs," the responses improved from rarely (26.92%) in pre-training test to "frequently" (42.30%) in the post-test. To another question "Whenever your patient reports a suspected ADR, how often do you report the same to a suitable authority," the responses were significantly ( $p < 0.05$ ) from rarely to "frequently." Another question "how often have you tried to report an ADR to the ADR monitoring center," the response was non-significantly improved in post-training test compared to pre-training test ( $> 0.05$ ). The complete results are presented in Table 4.

#### DISCUSSION

This study was carried out to assess the KAP of practicing community pharmacists toward ADR reporting. The study also evaluated the effectiveness of education intervention program on ADR reporting attitude and to motivate practicing community pharmacists toward ADRs reporting in Mysore city.

Globally, community pharmacies are the primary points of contact for the patients to share their health care related issues with pharmacists and receive prescription medicines and legally permitted OTC medicines. In community pharmacies, pharmacists apart from dispensing medicines monitor the patients for therapeutic outcomes as part of pharmaceutical care.

Pharmacovigilance is a part of the pharmaceutical care process and thus to monitor patients for potential ADRs. Worldwide, pharmacovigilance activity is becoming a priority for all health care professionals as the drug safety is paramount. The Uppsala Monitoring Center is an operational arm of the WHO with its 151 member countries maintains the global ADR database [13]. Majority countries have developed their own pharmacovigilance programs and encourage all their health care professionals to report ADRs. In few countries, community pharmacists are playing lead role in ADR reporting. In the Netherlands, more than 40% of ADR reports received by Lareb are from the community pharmacists indicating their ability to monitor and report 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 reporting is on par with reports received from clinicians [11].

Knowledge and skill are essential in providing meaningful and useful professional service. It is always important for all health care

**Table 2: Knowledge of community pharmacists toward ADR reporting (n=26)**

Questions	Correct response before training (n=26)	Correct response after training (n=26)	p value
What is an ADR?	18 (69.23)	26 (88.46)	>0.05
Which of the following factors pre-dispose for developing an ADR?	09 (34.61)	24 (92.30)	0.001
Which of the following ADR classification is correct?	09 (34.61)	24 (92.30)	<0.05
Which of the following are the consequences of ADRs?	10 (38.46)	21 (80.76)	0.01
Which of the following organ systems of the body will be affected due to an ADR?	22 (88.46)	26 (100)	0.01
Are you aware of national ADR reporting system in India?	11 (42.30)	22 (84.61)	0.01
Which of the following agency are responsible for ADR monitoring in India?	04 (15.38)	15 (57.69)	0.001
Which of the following health care professionals are permitted to report ADR?	19 (73.07)	26 (100)	0.001

ADR: Adverse drug reaction

**Table 3: Community pharmacists attitudes toward ADR reporting system (n=26)**

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?	22 (84.61)	23 (88.46)	04 (15.38)	03 (11.53)	00	00	00	00	>0.05
Is reporting of ADRs is an extra work for me	21 (80.76)	00	05 (19.23)	07 (26.92)	00	15 (57.69)	00	04 (15.38)	<0.05
I need special knowledge and skills for reporting of an ADR	19 (73.07)	14 (53.84)	04 (15.38)	10 (38.46)	03 (11.53)	01 (3.84)	00	01 (3.84)	>0.05
Will incentives for reporting ADR be a motivation for you?	09 (34.61)	02 (7.69)	02 (7.69)	10 (38.46)	15 (57.69)	08 (30.76)	00	06 (23.07)	<0.05
Do you think that doctors will have a negative opinion on you if you report an ADR?	21 (80.76)	02 (7.69)	04 (15.38)	13 (50.00)	01 (3.84)	11 (42.30)	00	00	<0.05
If I am encouraged training to report, I will take the responsibility of reporting ADR	25 (96.15)	13 (50)	00	13 (50.00)	01 (3.84)	00	00	00	<0.05

ADR: Adverse drug reaction

Table 4: Community pharmacists practices toward ADR reporting (n=26)

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?	09 (34.61)	14 (53.84)	12 (46.15)	10 (38.46)	05 (19.23)	02 (7.69)	00	00	>0.05
How often you take the responsibility of talking about safe use of medicines with patients	12 (46.15)	15 (57.69)	13 (50)	10 (38.46)	01 (3.84)	01 (3.84)	00	00	>0.05
How often you counsel your patients about possible adverse effects of the drugs?	09 (34.16)	11 (42.30)	09 (34.61)	11 (42.30)	07 (26.92)	04 (15.38)	01 (3.84)	00	>0.05
Whenever your patient reports a suspected ADR, how often do you report the same to a suitable authority	02 (7.69)	15 (57.69)	10 (38.46)	07 (26.92)	07 (26.92)	04 (15.38)	01 (3.84)	00	<0.05
How often have you tried to report an ADR to the ADR monitoring center	04 (15.38)	04 (15.38)	05 (19.23)	15 (57.69)	04 (15.38)	04 (15.38)	13 (50)	03 (11.53)	<0.05
How often you have collected all the necessary information to improve the quality of reporting?	02 (7.69)	04 (15.38)	05 (19.23)	15 (57.69)	04 (15.38)	04 (15.38)	15 (57.69)	03 (11.53)	<0.05

ADR: Adverse drug reaction

professionals to have the necessary knowledge and attitude to do any professional service. It is also true with pharmacovigilance activity. Despite of 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 under-reporting was found as "lack of knowledge and poor attitude" in health care professionals [12].

Thus, the current was study focused to assess pre- and post-educational intervention on "KAP" of community pharmacists toward ADR reporting. The findings suggest that the knowledge component score of the participants has increased from pre-training test score of  $4.30 \pm 2.02$  to post-test score of  $7.38 \pm 0.94$ , 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 the assessment of KAP of pharmacists toward ADR reporting suggest that community pharmacists are having inadequate knowledge regarding ADRs, pre-disposing factors, and reporting of ADRs [13-15].

In a cross-sectional pilot study conducted in Sultanate of Oman by Jimmy Jose *et al.*, the findings suggest that though the majority of respondent pharmacists have basic knowledge about ADR reporting but requires continuous educational training 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 [17].

Another 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 of ADR reporting system, and only a few pharmacists have reported ADRs to national pharmacovigilance system MADRAC [18].

In another South Indian based study conducted by Ravinandan *et al.*, the findings reveal that the community pharmacists were having low knowledge and poor attitude toward ADR reporting [19].

These finding clearly emphasizes the need of motivation to 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 the newsletter, etc.

In our study, in the post-education intervention, the majority community pharmacists have considered ADR reporting as their professional responsibility than were drug dispensers. This attitude in pharmacists was changed due to educational intervention and briefing them about pharmacists role in national pharmacovigilance program. The licensing authorities such state pharmacy councils or pharmaceutical associations or Boards of Pharmacies should take the lead in this direction to motivate the practicing pharmacists to be part in the national pharmacovigilance programs.

One of the barriers that are hindering ADR reporting by community pharmacists was an apprehension among the pharmacists about their professional relationship with their prescribers if they report an ADR. In India, majority practicing community pharmacists hold a diploma in pharmacy qualification to run the pharmacy and their primary focus is a trade than the patient care. Thus, the prescribers always looked them as drug sellers than as health care providers. Such barriers can be overcome by instituting professional standards for practicing pharmacists by the state pharmacy councils and supporting them to upgrade their knowledge and skills through continuous professional development programs. This strategy not only helps the practicing pharmacists have adequate confidence to answer drug-related queries from doctors and also motivates them to practice pharmaceutical care.

## CONCLUSION

The study findings conclude that post-educational intervention has significantly improved KAP of the respondent community pharmacists toward ADR reporting. So, educational intervention is one of the best ways to improve the awareness and motivate the community pharmacists toward ADR reporting.

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## REFERENCES

- Parthasarathi G, Olsson S. Adverse drug reactions. In: Parthasarathi G, Nyfort-Hansen K, Nahant MC, editors. *A Textbook of Clinical Pharmacy Practice*. Hyderabad, India: Universities Press; 2012. p. 104-22.
- Edwards IR, Aronson JK. Adverse drug reactions: Definitions, diagnosis, and management. *Lancet* 2000;356:1255-9.
- Kvasz M, Allen IE, Gordon MJ, Ro EY, Estok R, Olkin I, et al. Adverse drug reactions in hospitalized patients: A critique of a meta-analysis. *MedGenMed* 2000;2:E3.
- McDonnell PJ, Jacobs MR. Hospital admissions resulting from preventable adverse drug reactions. *Ann Pharmacother* 2002;36:1331-6.
- Ramesh M, Pandit J, Parthasarathi G. Adverse drug reactions in a south Indian hospital-their severity and drug safety. *Interscience*. DOI:10.1002/pds.871. Available from: <http://www.interscience.wiley.com>.
- Farcas A, Bojita M. Adverse drug reactions in clinical practice: A causality assessment of a case of drug-induced pancreatitis. *J Gastrointest Liver Dis* 2009;18:353-8.
- Kalaiselvan V, Prasad T, Bisht A, Singh S, Singh GN. Adverse drug reactions reporting culture in pharmacovigilance programme of India. *Indian J Med Res* 2014;140:563-4.
- Hazell L, Shakir SA. Under-reporting of adverse drug reactions: A systematic review. *Drug Saf* 2006;29:385-96.
- Sundos Q, Zakiametwaly MR, Mohammad S. Spontaneous reporting of adverse drug reactions in UAE: Obstacles and motivation among community pharmacists. *Int J Pharm Sci Res* 2014;5(10):4203-8.
- Kumar B, Divya PK, Shafaat K. Professional scopes and roles of community pharmacists in various health care services: An updated review. *J Pharm Res* 2011;4(5):1331-5.
- van Grootheest K, Olsson S, Couper M, de Jong-van den Berg L. Pharmacists' role in reporting adverse drug reactions in an international perspective. *Pharmacoepidemiol Drug Saf* 2004;13:457-64.
- Raja Rakesh CP, Adepu R. Design and implementation of adverse drug reaction reporting system in community pharmacies. *Indian J Pharm* 2009;2(2):32-7.
- Available from: <http://www.who.unc.org/DynPage.aspx?id=100653&mn1=7347&mn2=7252&mn3=7322&mn4=7442>.
- Qassim S, Metwaly Z, Shamsain M. Reporting adverse drug reactions: Evaluation of knowledge, attitude and practice among Community Pharmacists in UAE. *IOSR J Pharm* 2014;4(4):2319-22.
- Al-Hazmi NN, Aylor IL. A study of community pharmacist's awareness and contributions to adverse drug reactions reporting systems in the Makkah, Kingdom of Saudi Arabia. *J Clin Trials* 2013;3(1):127.
- Jose J, Jimmy B, Al-Ghailani AS, Al Majali MA. A cross sectional pilot study on assessing the knowledge, attitude and behavior of community pharmacists to adverse drug reaction related aspects in the Sultanate of Oman. *Saudi Pharm J* 2014;22:163-9.
- Elkalmi RM, Hassali MA, Mibrahim MI. Impact of educational intervention for improving pharmacist knowledge in adverse drug reactions reporting: Experience from Malaysia. *Open Drug Saf J* 2011;2:47-53.
- Elkalmi RM, Hassali MA, Ibrahim MI, Jamshed SQ, Al-Lela OQ. Community pharmacists' attitudes, perceptions, and barriers toward adverse drug reaction reporting in Malaysia: A quantitative insight. *J Patient Saf* 2014;10:81-7.
- Ravinanadan AP, Achutha V, Ramani VK, Uttangi S, Kumar SL. Study of knowledge, attitude, and practice of pharmacists towards adverse drug reaction reporting in Davangere City. *Asian J Pharm Clin Res* 2015;8(3):262-5.