

**ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICES  
AMONG COMMUNITY PHARMACIST ABOUT REPORTING OF  
ADVERSE DRUG REACTION IN SOUTH INDIA: A QUESTIONNAIRE  
BASED STUDY**

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Article Received on  
27 August 2020,

Revised on 17 Sept. 2020,  
Accepted on 07 October 2020

DOI: 10.20959/wjpr202013-18977

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**ABSTRACT**

Adverse drug reaction (ADR) is one of the leading cause of morbidity and mortality which leads to too much health care costs. The study was conducted to evaluate the knowledge, attitude and practice (KAP) of community pharmacists regarding reporting of adverse drug reaction in South India with the aim of identifying reasons for under-reporting of ADRs. A cross sectional study was conducted among community pharmacist for a period of three months from August 2019 to October 2019, using a well-structured validated questionnaire with a total of twenty two questions. The study population was 244 community pharmacists. The mean age of participants was 27.08 years. More than half of participants 132(54.1%) were D Pharm and worked in independent pharmacy 152(62.29%), 80(32.79%) participants who said they were familiar with the ADR reporting process were asked whether

they knew the regulatory body to which ADR should be reported. Answers included pharmacovigilance (20%) followed by CDSCO (15%), Indian Pharmacopoeia Commission

(15%) and WHO (10%). The majority of participants (90.57%) had never reported ADR. Major reason for not reporting ADR was lack of awareness about method of reporting (52.46%). Thus it can be concluded that community pharmacists have poor knowledge and practice on ADR reporting, but their attitude towards ADR reporting was found to be good, which indicates need for training programs on pharmacovigilance. Pharmacovigilance authorities should adopt essential steps to plan interventional programs to enhance the knowledge of community pharmacist about ADR reporting process.

**KEYWORDS:** Pharmacovigilance, Knowledge, attitude and practice, ADR reporting

## INTRODUCTION

Adverse drug reaction is one of the leading causes of morbidity and mortality which leads to too much health care costs.<sup>[1]</sup> Therefore post marketing surveillance is very important for monitoring the risk and benefit of pharmaceutical products after they have been released on the market.<sup>[2]</sup> Each and every ADR can't be documented by the manufacturer via early safety studies. So it is very much essential to monitor ADR after marketing of drugs.<sup>[1]</sup> Pharmacovigilance is useful to assure the safety of medicines and protect consumers from their harmful effects. According to the definition provided by the World Health Organization, "an ADR is any harmful, unintentional, and undesirable effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or therapy."<sup>[1]</sup> Spontaneous reporting of ADRs remains the most widely used system and is the cornerstone of safety monitoring of drugs in clinical practice. Under reporting of ADR is a key barrier for the evolution of pharmacovigilance programs. Given the lower rate in India, one of the reasons might be attributed to the awareness about pharmacovigilance and ADR monitoring among the Indian healthcare providers.<sup>[3]</sup> The ADR reporting rate in India is below 1% compared to the worldwide rate of 5%. ADR management can cost the institution or the patient as much as US \$15-150 in India.<sup>[4]</sup> Traditionally, the role of the pharmacist was limited to the preparation and dispensing of drugs prescribed by the physician. Recently, the role of the pharmacist has expanded to other aspects of patient care. These roles include reporting ADRs, improving patients' health, and economic outcome.<sup>[5,6]</sup> Pharmacists can play an important role in ADR reporting and pharmacovigilance by increasing the number as well as the quality of submitted reports.<sup>[7,8,9]</sup> However, in many countries the knowledge of pharmacists about pharmacovigilance and ADR reporting is poor and the rate of reporting is low.<sup>[10,11]</sup> Assessing the knowledge, attitude and practice (KAP) of community pharmacists relating to a

spontaneous reporting of ADRs is very important. Previous studies had shown that pharmacists can make a major positive contribution to the quality and number of ADRs reported.<sup>[12]</sup> Pharmacists have sufficient knowledge of the ADR reporting process, they can improve other health care professional's knowledge about ADR reporting.

Strong association between ADR knowledge, attitude and practice (KAP) of community pharmacists had been documented by various studies. So improvement in the KAP of community pharmacists is important for pharmacovigilance program in any country. Community pharmacists (CP) are usually first to be contacted by patients in most ADR and they are very important source of ADR reporting.<sup>[1]</sup>

Pharmacist can play an important role in ADR reporting and pharmacovigilance by increasing the number as well as the quality of submitted reports. However in many countries the knowledge of pharmacist about ADR reporting and pharmacovigilance is poor and the rate of reporting is low. The scenario in India is same as in other countries.<sup>[2]</sup> Intrinsic factors such as knowledge, attitude and practice can help in understanding the relationship of pharmacists with patients and other healthcare professionals and formulating strategies to encourage pharmacists to report ADRs. A few studies carried out in India have shown poor knowledge, attitude, and deficient practices involving ADR reporting among community pharmacist. However, very few studies look into the reasons that impact the knowledge, attitude and practice of pharmacists with regard to ADR reporting. Hence, this study was conducted to analyse the knowledge, attitude, and practice (KAP) related to ADR reporting among community pharmacists in South India.<sup>[3]</sup>

## AIM AND OBJECTIVE

Objective of the study was to determine the knowledge, attitude and practice of ADR among community pharmacist and the study aims to determine the reasons for under-reporting of ADRs.

## METHODS

### Study period

- The study was conducted over a period of 3 months.

**Study population and study centre**

- The study was conducted among 244 community pharmacists (randomly selected) in and around Thiruvananthapuram, Kerala, India.

**Study design**

- It was a cross sectional study conducted among community pharmacist from Thiruvananthapuram, Kerala.

**Study Tool**

- A well-structured validated questionnaire was used for the study. The questionnaire was pretested and verified for errors.

**Inclusion criteria**

- All community pharmacists with qualification as registered pharmacists were included in the study.

**Exclusion criteria**

- Pharmacy technicians and assistants with no eligible qualification were excluded.

**Study tool**

A self-administered questionnaire was made using evidence and careful examination from the literature survey and features used in former research studies. It was then validated by three experts, with experience in drug use research, to evaluate the clarity, relevance and conciseness of matter incorporated in the questionnaire. Their observations and comments were taken in to the account and final questionnaire was prepared.

The KAP questionnaire consisted of a total of twenty two questions. Section A included six questions on demographic details. Section B comprised of six questions related to basic knowledge and information about ADR reporting (five closed ended questions and one open ended question) Section C consisted of five questions (closed ended) related to pharmacist's attitude. Section D has five questions (four closed ended and one open ended) related to practice / perception regarding ADR reporting.

**Data analysis**

The response to the questionnaire was analyzed by performing descriptive statistics using SPSS version 20.

## RESULTS

### 1. Demographics of the participants

Our study population consisted of 34.4% male and 65.6% of female community pharmacist (Table I). The average age of the participants was 27.08 years. Majority 54.1% were D Pharm, 31.1% were B Pharm, 9.8% were M Pharm and 4.9% were Pharm D graduates. The majority (62.30%) of pharmacists were employed in independent pharmacy.

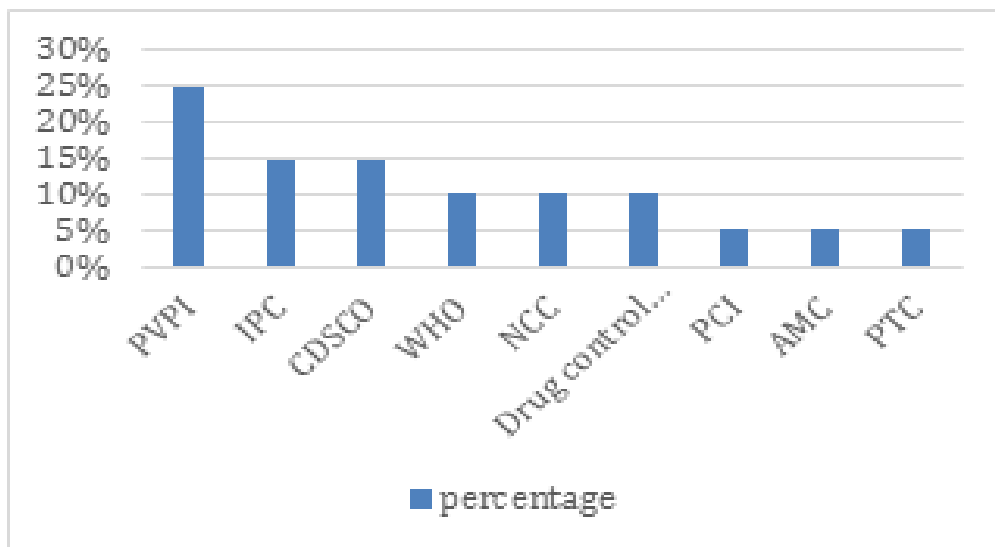
**Table I: Demographics of the participants.**

Variable	Category	n (%)
Mean Age	27.08 years	
Gender	Female	160 (65.6%)
	Male	84 (34.4%)
Education	D Pharm	132(54.1%)
	B Pharm	76 (31.1%)
	M Pharm	24 (9.8%)
	Pharm D	12 (4.9%)
Experience	0-5 years	204(83.61%)
	6-10 years	24(9.83%)
	11-15 years	12(4.92%)
	>20 years	4(1.64%)
Availability of internet service	Yes	188(77%)
	No	56(23%)
Category of pharmacy	Independent	152(62.30%)
	Hospital attached	48(19.67%)
	Chain pharmacy	44(18.03%)

### 2. Community pharmacist knowledge about ADR reporting

There were six questions to evaluate the knowledge of community pharmacist regarding ADR reporting (Table II). Among the 244 respondents, 78.69% (n=192) were aware that all ADRs of allopathic medications need to be reported. 32.79% community pharmacists said that they were aware about how and where to report an ADR. Those who said they were aware about such reporting were asked whether they knew the regulatory body responsible for collecting and monitoring ADR in India. Answers were given by community pharmacists that included pharmacovigilance (25%), Indian Pharmacopoeia commission (15%), CDSCO (15%), WHO(10%), National coordination committee (NCC-10%), Drug control department (10%), Pharmacy council of India (PCI-5%), ADR monitoring centre (AMC-5%) and Pharmacy and Therapeutic Committee (PTC-5%) (Fig 2).

29.6% respondents believed that ADR should be reported only when they are severe and cause danger to life. However about 32.79% of pharmacists did not know that they could report ADR through an online system.



**Fig. 2: Regulatory body responsible for collecting and monitoring ADR in India.**

**Table II: Community pharmacist knowledge about ADR reporting.**

Sr. No.	Questions	Response			
		Yes		No	
		n	%	n	%
1	Do you think all ADRs of allopathic medications need to be reported as it is extensively studied during clinical trials?	192	78.69%	52	21.31%
2	Do you think that ADRs associated with herbal products also need to be reported?	196	80.33%	48	19.67%
3	Do you know how and where to report an ADR?	80	32.79%	164	67.21%
4	Do you think ADR need to be reported only when they are severe and cause danger to life?	64	29.6%	152	70.4%
5	Can community pharmacist submit adverse drug reactions by electronic (online) reporting in India?	164	67.21%	80	32.79%

### 3. Community pharmacist Attitude towards ADR reporting

There were five questions related to attitude of pharmacists towards ADR reporting (Table III). 91.39% pharmacist felt that community pharmacist should be involved in ADR reporting. Most of the pharmacists (91.80%) felt that reporting ADR is their professional responsibility. 95.91% respondents believed that serious ADR encouraged them to report it to the relevant authority. 94.67% participants felt that ADR reporting should be made compulsory for all practicing pharmacist. 96.7% of community pharmacist were interested in

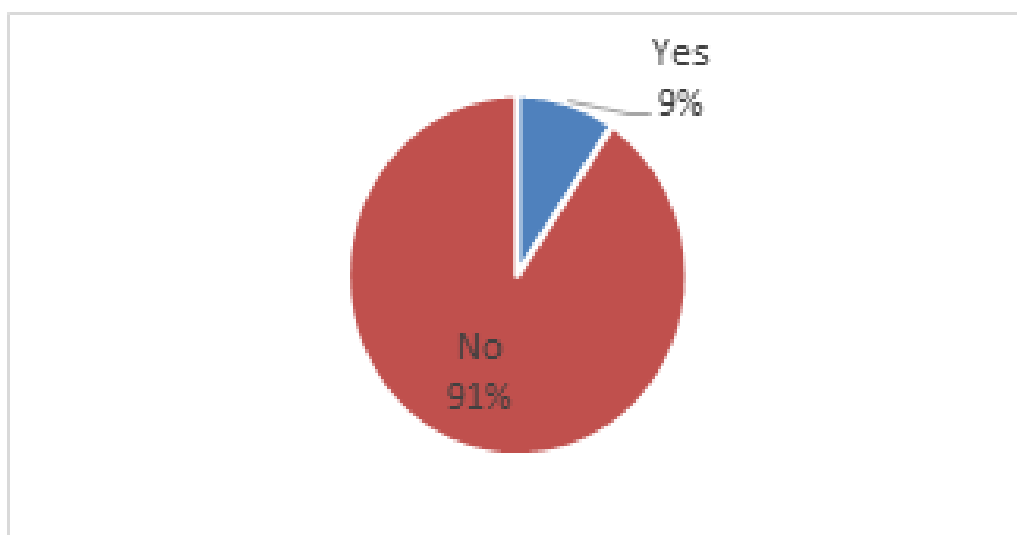
participating in the ADR reporting system. Table 3 summarizes attitude of community pharmacist towards ADR reporting.

**Table III: Community pharmacist Attitude towards ADR reporting.**

	Questions	Response			
		Yes		No	
		n.	%	n.	%
1	Do you think community pharmacist should be involved in ADR reporting?	223	91.39%	16	8.60%
2	Do you think ADR reporting is professional responsibility of a pharmacist?	224	91.80%	20	8.19%
3	Do you think serious ADR encourage pharmacist to report it to the relevant authority?	234	95.91%	10	4.09%
4	Do you think ADR reporting should be made compulsory for all practicing pharmacist?	231	94.67%	13	5.33%
5	Are you interested in participating in the ADR reporting system?	236	96.7%	8	3.3%

#### 4. Community pharmacist practice towards ADR reporting

There were five questions regarding practice of respondents towards ADR (Table 4). 82.37% of pharmacists replied that reporting form of ADR are not available at their work place. 65.98% have observed ADR cases during their practice. Only 9.43% reported that they are sending a suspected ADR report to the manufacturer.



**Fig. 4: Percentage of ADR reporting by community pharmacist.**

Only 13.11% have attended any ADR workshop or training. About question regarding reasons for not reporting ADR by pharmacist, majority of participants (52.46%) replied that they are not aware about method of reporting of ADR. Other reasons include, most ADR

were minor (16.80%) and are familiar (11.48%). 1.64% replied that ADR reporting in India is not widely promoted by relevant authorities. 11.48% responded that they don't have enough time for reporting and 6.14% participants feared facing legal problems while reporting.

**Table IV: Community pharmacist practice towards ADR reporting.**

	Questions	Response			
		Yes		No	
		n.	%	n.	%
1	Is reporting form of ADR available at your place of work?	43	17.63%	201	82.37%
2	Have you observed ADR cases during your practice?	161	65.98%	83	34.02%
3	Do you report ADR that you come across?	23	9.43%	221	90.57
4	Have you attended any ADR workshop or training ?	32	13.11%	212	86.88%
5	What are the main reasons for not reporting an ADR?	128	52.46%		
	Lack of awareness about the method of reporting.				
	Pharmacist doesn't have enough time.	28	11.48%		
	Most ADR are minor and should not be reported	41	16.80%		
	All ADRs are familiar and already reported	28	11.48%		
	Fear of facing legal problems	15	6.14%		
	Others	4	1.64%		

## DISCUSSION

Adverse drug reaction is one of the leading cause of morbidity and mortality which leads to increased health care costs. Community pharmacists (CP) are generally first to be contacted by patients in majority of ADR. So assessing their knowledge, attitude, and practice (KAP) related to ADR reporting is very valuable. Our study population consisted of more female participants than male community pharmacist. The average age of the participants was 27.08 years. Of all the participants answering the survey more than half of the study population were D Pharm and most of them were employed in independent pharmacy.

Out of the 244 respondents, majority were aware that all ADRs need to be reported even though they are widely studied during clinical trials. Less than twenty percent pharmacists think that it is not necessary to report ADR associated with herbal products. 32.79% participants replied that they are familiar with the reporting process. Such participants were asked whether they knew the reporting procedure and the agency to which ADR is to be reported. Only 15% correctly answered as CDSCO. According to our study, the percentage of participants who were aware that community pharmacist can submit adverse drug reactions through an online system was less.



The overall knowledge on ADR reporting was found to be poor and there are studies reporting similar to our findings.<sup>[11,13,14]</sup> The rate of ADR reporting by pharmacists in various countries has been reported to vary from 3% to 14.7%. A previous study from Saudi Arabia reported a lower level of awareness about the process of ADR reporting compared to our findings (13.2% vs. 22%).<sup>[15,16]</sup>

In general, the respondents had a good attitude towards ADR reporting. Studies conducted in Iran and Hong Kong had shown that pharmacists can make a major positive contribution to the quality and number of ADRs reported.<sup>[10,11]</sup> Majority of pharmacists felt that ADR reporting is professional responsibility of community pharmacist and believed that they should be involved in ADR reporting. Also most of the participants said that serious ADRs motivated pharmacists to report to the pertinent authority, and ADR reporting should be made compulsory for all practicing pharmacist. Also, maximum participants were found interested to take part in the ADR reporting system.

Compared to good attitude of the respondents they had poor practice. Only few participants replied that ADR forms are available at their work place. Although 65.98% have observed ADR cases during their practice, very few (9.43%) had reported ADR. Only 13.11% participants had attended an ADR workshop or training. Greater part of study population reported lack of awareness as major reason for not reporting ADR. A similar study conducted in India and Nigeria also stated lower level of ADR reporting.<sup>[3]</sup> Another study suggests that involvement of pharmacy students in community pharmacy internships may increase the awareness of future pharmacists regarding ADR detection and reporting.<sup>[17]</sup>

## CONCLUSION

According to our study, the attitude of community pharmacist towards ADR reporting was relatively better, but their knowledge and practice about ADR reporting were found to be limited. There is a need for awareness programmes for pharmacists in spontaneous reporting and pharmacovigilance which may help to enhance the degree of ADR reporting. Likewise, participation of pharmacy students in community pharmacy internships may upsurge the awareness of future pharmacists about ADR detection and reporting.

## ACKNOWLEDGMENT

The authors would like to express our earnest appreciation to all the pharmacists who provided their valuable response for the fruitful completion of the study.

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