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## A Survey on Awareness about Pharmacovigilance among Community Pharmacists in Resource Limited Settings of India

Original Article

Authors

**\*Nasr Khallafallah Nasr Elhidrbi<sup>1</sup>, Mouaid Mohamed Eltayeb<sup>1</sup>, Tirupa M<sup>2</sup>,  
Dr Mohanraj Rathinavelu<sup>3</sup>, Dr. Y. Padmanabha Reddy<sup>4</sup>**

<sup>1</sup>II Year Student, Masters of Pharmacy, Department of Pharmacy Practice, Raghavendra Institute of Pharmaceutical Education & Research, RIPER, Ananthapuramu, Andhra Pradesh, India – 515721

<sup>2</sup>Pharm. D Intern, Doctor of Pharmacy, Department of Pharmacy Practice, Raghavendra Institute of Pharmaceutical Education & Research, RIPER, Ananthapuramu, Andhra Pradesh, India – 515721

<sup>3</sup>Assistant Professor & In-Charge, Department of Pharmacy Practice, Raghavendra Institute of Pharmaceutical Education & Research, RIPER, Ananthapuramu, Andhra Pradesh, India – 515721

<sup>4</sup>Professor & Principal, Raghavendra Institute of Pharmaceutical Education & Research, RIPER, Ananthapuramu, Andhra Pradesh, India – 515721

\*Corresponding Author

**Mr. Nasr Khallafallah Nasr Elhidrbi**

II Year Student, Masters of Pharmacy, Department of Pharmacy Practice, Raghavendra Institute of Pharmaceutical Education & Research, RIPER, Ananthapuramu, Andhra Pradesh, India – 515721

Email: [machomoley@gmail.com](mailto:machomoley@gmail.com), Cell no: +91 8897903917

### ABSTRACT

*Over the past four decades there has been a trend for pharmacy practice to move away from its original focus on medicine supply towards a more inclusive focus on patient care. Due to the introduction of a large number of potent toxic chemicals as drugs in the last two or three decades the detection of adverse drug reactions (ADRs) has become increasingly significant. Physicians, pharmacist and nurses are in a position to play a major key role in pharmacovigilance programs. The current cross sectional questionnaire survey of six months duration was designed to assess the pharmacovigilance awareness among the pharmacists in community settings in a resource limited settings of south India by administering a Pre-designed questionnaire. Among the 120 pharmacists working in community settings only 80% (96) provided their responses. Of the responses 75% (72) were analyzed and the rest were not included in the analysis because of incomplete information. This study showed little awareness about the Pharmacovigilance system among the pharmacists in community settings of resource limited setting in south India. The pharmacists primarily did not know the definition and purpose of Pharmacovigilance. In conclusion, Community Pharmacists have very little basic knowledge about pharmacovigilance. The simulations about pharmacovigilance can be incorporated in the syllabus of diploma and degree curriculum of pharmacy by Pharmacy Council of India (PCI) by which the practice of pharmacy and pharmaceutical care concepts can be well established.*

**Keywords:** Community pharmacists, cross sectional survey, pharmacovigilance, professional practice.

## INTRODUCTION

Over the past four decades there has been a trend of pharmacy practice to move away from its original focus on medicine supply towards a more inclusive focus on patient care. The role of the pharmacist has evolved from that of a compounder and supplier of pharmaceutical products towards that of a provider of services and information and ultimately that of a provider of patient care. This new approach has been given the name *pharmaceutical care* defined as the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life" (Hepler and Strand, 1990) <sup>[1]</sup>. In adopting this definition in 1998, the International Pharmaceutical Federation (FIP) added one significant amendment: "achieving definite outcomes that improve or maintain a patient's quality of life." The concept of the seven-star pharmacist, introduced by WHO (World Health Organization) and taken up by FIP in 2000 in its policy statement on Good Pharmacy Education Practice, sees the pharmacists as a caregiver, communicator, decision-maker, teacher, life-long learner, leader and manager <sup>[2]</sup>.

Medication safety is a more significant issue, because of immense competition among pharmaceutical manufacturers; medicinal products may be registered and marketed in many countries simultaneously. As a result, adverse reactions may not always be readily identified and so are not monitored systematically. Pharmacovigilance is a systematic and structured process for the monitoring and detection of adverse drug reactions (ADRs) in a given context <sup>[3]</sup>.

Pharmacovigilance has constantly grown its importance in last 15 years, relating to the absolute amount of adverse drug reactions (ADRs) and to the fact of several hospital admissions are due to ADRs <sup>[4][5]</sup>.

The success of a pharmacovigilance program depends upon the involvement of the healthcare professionals and reporting the ADRs. Providing information on suspected ADRs is as much a

moral duty for the doctor as other aspects of patient care <sup>[6]</sup>.

The community pharmacist's role is to promote the development, maintenance and ongoing evaluation of a program to reduce the risks of ADRs by detecting, reporting and assessing any suspected ADRs. A pharmacist can educate the physicians and nurses and can encourage compliance with the ADR reporting program <sup>[7]</sup>.

The literatures reported that community pharmacists can play a vital and supportive role in ADR reporting because they are considered as the first point of contact within the health care system and daily contact with patients makes them ideally placed to learn of possible ADRs <sup>[8]</sup>.

Pharmacovigilance is still in its infancy in India and there exists very limited knowledge about this discipline. However, the Indian national Pharmacovigilance programme lacks continuity due to lack of awareness and inadequate training about drug safety monitoring among healthcare professionals in India <sup>[9]</sup>. Therefore this study was conducted to assess awareness of pharmacovigilance among the community pharmacists in Anantapur, Andhra Pradesh., India.

## MATERIAL & METHODS

**Study design:** Cross sectional, questionnaire based survey.

**Study site:** The study was carried out among registered pharmacists working in community backgrounds of a resource limited settings of India.

Study Period: 06 Months.

**Study Population & Sampling:** 72 Registered pharmacists.

### Study Criteria

**Inclusion criteria:** Registered pharmacists with qualification of

- D.Pharmacy
- B.Pharmacy was included in study.

### Exclusion Criteria:

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

**Study Tools & Procedure:**

The study instrument was a pre-designed questionnaire which was structured to obtain information on the knowledge about Pharmacovigilance and Adverse Drug Reactions (ADRs).

Questionnaire: The questionnaire was adapted from a similar study investigating the knowledge and practice of Pharmacovigilance and ADR reporting. It was designed to capture the information contained two sections comprising of demographic data and questions on knowledge on pharmacovigilance. Questionnaire was prepared and evaluated by the faculties' expertise in the field of drug use and research and ADR reporting and monitoring studies of Raghavendra Institute

of Pharmaceutical Education & Research (RIPER) Anantapuramu, Andhra Pradesh., India.

**RESULTS & DISCUSSION**

Among the 120 pharmacists working in community settings only 80% (96) provided their responses. Of the responses 75% (72) were analyzed and the rest were not included in the analysis because of incomplete information. Demographic details of the participants involved in the study was categorized based on gender distribution, age distribution, educational qualification, the results of which were thoroughly analyzed and reported in Table 1 (Demographic details of the participants).

**Table. 1.** Demographic Details

S. no	Demographic details	No. of Participants (n = 72)		
01	Gender Distribution			
	A. Male	56 (77.78%)		
	B. Female	16 (22.22%)		
02	Age Distribution	(n = 72)	Male	Female
	22 – 30	18	12	06
	31 – 40	32	25	07
	41 – 50	13	10	03
	>50	09	09	-
03	Educational Qualification	(n = 72)	Male	Female
	D. Pharmacy	54	43	11
	B. Pharmacy	18	13	05

This study showed little awareness about the Pharmacovigilance system among the pharmacists in community settings of resource limited setting in south India. The pharmacists primarily did not know the definition and purpose of Pharmacovigilance. Since, the questionnaire comprises of details regarding functions and field

of pharmacovigilance in choices most of the pharmacists replied it with option of ALL which was correct. The response of the participants to the pre-designed questionnaire was reported in Table. 2 (Responses to the Pre-designed Questionnaire).

**Table. 02** Responses to the Pre-designed Questionnaire

S.no	Questions	Right Answer	Positive response	Negative response
01	Define Pharmacovigilance	The detection, assessment, understanding & prevention of adverse effects	18 (25%)	54 (75%)
02	The important purpose of Pharmacovigilance is	To identify safety of drugs	15 (20.83%)	57 (79.17%)
03	The functions of Pharmacovigilance are	All of the above	60 (83.33%)	12 (16.67%)
04	Pharmacovigilance includes	All	60 (83.33%)	12 (16.67%)
05	National pharmacovigilance program in India is governed by	CDSCO under the aegis of Health and Family Welfare	16 (22.22%)	56 (77.78%)
06	National Pharmacovigilance Programme (NPP) of India was officially inaugurated in the year:	New Delhi, 2004	18 (25%)	54 (75%)
07	The chairman of Pharmacovigilance program in India	DCGI (Drug Controller General of India)	21 (29.17%)	51 (70.83%)
08	Are you aware of existence of NPC in India	YES	NO	
		30	42	
09	If yes, then where is it located:	CDSCO	18	54
10	Do you know that community Pharmacist is one of the responsible healthcare professionals to report ADRs	YES	NO	
		39 (54.17%)	33 (45.83%)	

The response to the Governance and inauguration of National Pharmacovigilance Programme (NPP) India was very negative. Therefore, it seems necessary to hold awareness programmes to improve the education of pharmacists in community settings regarding the current scenario of pharmacy practice in India and its future perspective.

The pharmacist should also be encouraged for the ADRs reporting, since they are in closer contact with the patients for a longer duration and as they can play an important role in making the pharmacovigilance programs more efficacious.

### CONCLUSION

In conclusion, community pharmacists have very little basic knowledge about pharmacovigilance. The simulations about pharmacovigilance can be

incorporated in the syllabus of diploma and degree curriculum of pharmacy by Pharmacy Council of India (PCI) by which the practice of pharmacy and pharmaceutical care concepts can be well established. The pharmacist in community setting practice can also contribute to the patient care with good health outcome benefit and safety use of medication rationally.

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