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Review Article

**CLINICAL PHARMACIST ROLE IN PHARMACOVIGILANCE  
FOR ACCOMPANYING RATIONALITY****Purushothama Reddy K<sup>1\*</sup>, Dr. Rajesh Asija<sup>2</sup>, Dr. M. Purushothaman<sup>3</sup>,  
Dr. S. Arshiya Banu<sup>4</sup>**<sup>\*1</sup>Associate Professor, Department of Pharmacy Practice, Rao's College of Pharmacy,  
Nellore, A.P – 524 320.<sup>2</sup>Professor, Department of Pharmaceutics, Sunrise Pharmacy College, Sunrise University,  
Alwar, Rajasthan, India.<sup>3</sup>Principal & Professor, Department of Pharmaceutics, Scient Institute of Pharmacy,  
Ibrahimpatnam, R. R. District – 501 506, Hyderabad, Telangana, India.<sup>4</sup>Assistant Professor, Department of Pharmacy Practice, P. Rami Reddy Memorial College of  
Pharmacy, Kadapa, A.P – 516003.**Abstract:**

World Health Organization (WHO) defines Pharmacovigilance as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems. Pharmacovigilance plays an important role in ensuring patients drugs safety as it an integral part of the system. According to WHO, Adverse Drug Reaction (ADR) is defined as any response to a drug which is noxious and unintended and occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or the modification of physiological function.

Complete information of unintended and severe adverse events could be identified through evaluation of drug effect by the Pharmacovigilance. It would not be possible to identify all the drug effects during a clinical trial conducted in in-vivo due to the limited time period and other factors. Pharmacists do not do mere compounding or dispensing of the drugs. They plays a infinite role in the pharmaceutical industry and clinical research as well. The profession of pharmacy practice reached far beyond serving the community. Pharmacist play a paramount role in pharmacovigilance. Their role in pharmacovigilance varies from country to country, but their prime responsibility is to serve regardless for the safety of the community. Pharmacists can create a trusted environment by counseling the patients by reducing the medication errors and by upgrading the safety and quality of life of the patient.

**Keywords:** Pharmacovigilance, Pharmacist, Adverse Drug Reactions (ADRs), Prophylaxis.

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**INTRODUCTION:**

Pharmacovigilance is the science of detection, assessment, understanding and prevention of adverse effects or any other possible drug related problems [1] such as medication error, overdose, sub dose etc. It plays an integral role in ensuring the drug safety, safeguarding the patient by providing high quality medical care. It is an essential tool used to monitor the effective use of drug therapy. Pharmacovigilance is recognized as a clinical discipline as it serves as an indicator for practicing clinical care within the country [2,3].

WHO established the pharmacovigilance system in 1968 after the thalidomide tragedy (phocomelia in babies whose mothers used thalidomide during pregnancy)? According to WHO, Adverse Drug Reaction (ADR) is any response to a drug which is noxious and unintended and occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or the modification of physiological function. The Uppsala Monitoring Center (UMC) is the WHO Collaborating Centre for International Drug Monitoring. UMC works by collecting, assessing and communicating the information and national programs from member countries with respect to the betterment, noxiousness, effectiveness and risks of drugs. The success of Pharmacovigilance program depends highly on the collaboration of all health care professionals and their effective co-operation and communication between the practitioners and pharmacovigilance centre [4]. Reporting the ADRs is considered to be an active step in maintaining and achieving the usage of safe drug therapy [5].

Pre-marketing clinical studies proved to be disadvantageous as these studies are done with minimal population, lack of long term exposure to the targeted molecule, the existence of co-morbid conditions, population diversity and concomitant use of other medications. These factors are responsible for less understanding of the experimental molecule regarding its efficacy and interactions of drug-drug and drug-food. Even though pre-marketing clinical studies plays a crucial role in understanding drug product's safety and efficacy, they have its own limitations. Essential steps taken to monitor the effects of the medicine and ensuring the safe use of medicine is done by Post-marketing surveillance and continuous Pharmacovigilance processes [6,7].

**INDIAN FRAMEWORK:**

The Government of India in collaboration with the Indian Pharmacopoeia Commission (IPC), Ghaziabad, has initiated a nationwide program called

Pharmacovigilance Program of India (PvPI) in 2010. The program is being coordinated by the National Coordinating Centre (NCC), under the supervision of Central Drugs Standard Control Organization (CDSCO) and Directorate General of Health Services under the Ministry of Health and Family Welfare. Across the country, PvPI holds 150 functional ADR monitoring centers (AMCs) [4]. The National Pharmacovigilance system is the main route to collect information on ADRs occurrences in both hospital and community settings [6].

**ROLES OF PHARMACIST:**

In the professional front, the practice of pharmacist has reached far beyond serving the community from not mere preparing or dispensing of drugs as it has become more patient-centric [4]. Pharmacists contribute his work for the drug safety by preventing, identifying, documenting and reporting the ADRs [5]. The role of the pharmacist in the department of pharmacovigilance varies in different countries but, professionally their responsibility remains the same irrespective of the jurisdiction [7]. Pharmacist has the potential of reporting ADRs on their own, though his/her clinical experience may vary with respect to that of a physician [2]. The process of Pharmacovigilance program can be a success when effective risk information is communicated back to the health-care workers. The major step in progressing the prevention of ADRs is to acquaint the risk-benefit profile of drugs to all the clinical practitioners.<sup>4</sup> Pharmacist plays an essential role in drug therapy monitoring [4]. Pharmacists can be deployed to assist in monitoring the safe and effective use of available medicine, which certainly includes the management of ADRs. The worthwhile information collected by the pharmacist in the Pharmacovigilance should be appreciated [8].

Pharmacist act as an open-arm to clinical expertise in sharing the resources including databases. Pharmacist plays an essential role in developing communication materials like newsletters and other publications through the drug information and poison centers, which are utilized by different professions and professionals for disseminating drug alerts and other drug safety information which helps in providing the rational treatment.<sup>9</sup> Pharmacist must also involve in the collection of data that might be useful in triggering the initiation of longitudinal Pharmacoepidemiological studies.<sup>5</sup> Pharmacists can assure a positive environment to the patients by minimizing the medication errors, improving patient safety and quality of life during the counselling session [9,10].

In a study carried out by Mohmoud et al., 23% of the

pharmacists involved in the study were familiar with ADR reporting process and 77% of the pharmacists had never reported ADRs. Major reason for not reporting the ADRs is due to lack of awareness about the method of reporting [11]. Apart from reporting ADRs, the pharmacist can also pre-occupy themselves in keeping track of important files and documents related to patient safety by maximizing the benefit and minimizing the risk of medication use and by updating his knowledge on newer drug inventions, regimens and surgical procedures. Pharmacist should have a firm knowledge in monitoring and providing counseling about the use of over-the-counter medications [7].

### CONCLUSION:

Clinical pharmacists play a paramount role in monitoring the prescription of drugs as a part of their pharmacy profession. They suggest the health care professionals for rational therapy by providing the data on adverse drug reactions and drug related problems. Communication with the health care team helps to ensure the rational therapy by enhancing the quality of life of the patient. Pharmacist can provide better health environment in the hospital and they can strengthen their role by doing a research on pharmacovigilance in more clinically valued output. By conducting educational training programs and workshops, awareness can be created in the population on how to minimize the drug effects and on reporting the ADRs. Pharmacists can create a trusted environment by counseling patients on both the drug related problems and disease related problems as well as life style modifications. Constantly improving the knowledge on drugs will enable the pharmacists to bring new milestones in the future.

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