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PHARMACOVIGILANCE: IMPORTANCE AND ROLE OF THE CLINICAL PHARMACIST IN ASSESSING AND MANAGING ADVERSE DRUG REACTIONS

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Abstract

Pharmacovigilance is a key component of healthcare systems worldwide, focusing on the detection, assessment, understanding, and prevention of adverse drug reactions (ADRs). The rising incidence of ADRs has underscored the necessity for active monitoring to ensure patient safety and rational drug use. Clinical pharmacists play a vital role in pharmacovigilance through the identification, documentation, evaluation, and reporting of ADRs, as well as by educating healthcare professionals and patients. Their involvement in multidisciplinary healthcare teams enhances the early detection and management of ADRs, thereby minimizing morbidity, mortality, and healthcare costs. This review highlights the importance of pharmacovigilance, outlines the essential role of clinical pharmacists in ADR monitoring and management, and discusses the challenges and future perspectives in this domain.

***Keywords*:** Pharmacovigilance, Clinical Pharmacist, Adverse Drug Reactions, Patient Safety, Drug Monitoring, Medication Error.

INTRODUCTION

Pharmacovigilance (PV) refers to the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems [1]. With the growing complexity of therapeutic regimens and the introduction of new drugs, the incidence of adverse drug reactions (ADRs) has increased, posing significant risks to patient safety and healthcare systems globally [2].

Clinical pharmacists, as integral members of healthcare teams, are well positioned to play a proactive role in pharmacovigilance. Their expertise in pharmacology, therapeutics, and patient care enables them to identify, evaluate, and manage ADRs effectively (3). This review discusses the importance of pharmacovigilance, the role of clinical pharmacists, and strategies for enhancing ADR reporting and management.

IMPORTANCE OF PHARMACOVIGILANCE

1 ENSURING DRUG SAFETY

Pharmacovigilance aims to identify new information about drug safety profiles and prevent harm to patients [4]. Continuous monitoring of drugs after marketing authorization is critical because pre-marketing trials often involve limited populations and may not reveal all adverse effects [5].

2 REDUCING HEALTHCARE COSTS

ADRs contribute significantly to healthcare expenditure due to prolonged hospital stays, additional treatments, and litigation costs [6]. Effective pharmacovigilance helps minimize these expenses by preventing avoidable ADRs.

3 Improving Rational Use of Medicines

Pharmacovigilance promotes evidence-based prescribing and rational drug use by providing updated safety data to healthcare professionals [7].

ROLE OF CLINICAL PHARMACIST IN PHARMACOVIGILANCE

1 ADR Detection and Monitoring

Clinical pharmacists are trained to recognize early symptoms of ADRs during routine clinical rounds and patient counseling sessions [8]. They assess causality using standardized scales such as the Naranjo Algorithm or WHO-UMC criteria [9].

2 ADR Documentation and Reporting

Pharmacists play a vital role in recording ADRs accurately and submitting them to national pharmacovigilance centers or institutional drug safety committees [10]. Their involvement improves the quantity and quality of ADR reports, enhancing national drug safety databases [11].

3 Patient and Healthcare Professional Education

Clinical pharmacists educate patients on possible side effects and encourage adherence to therapy while promoting timely ADR reporting [12]. They also train other healthcare providers on recognizing and documenting ADRs [13].

4 Participation in Drug Safety Committees

Pharmacists are key contributors to hospital drug safety committees, where they analyze ADR trends, review medication errors, and recommend safer therapeutic alternatives [14].

ASSESSMENT AND MANAGEMENT OF ADVERSE DRUG REACTIONS

1 Causality Assessment

Causality assessment determines whether a specific drug is responsible for an observed reaction. Tools like the Naranjo Scale, WHO-UMC criteria, and the European Medicines Agency (EMA) guidelines are commonly used [15].

2 Severity and Preventability Assessment

ADR severity can be classified using Hartwig's severity scale, while preventability is assessed using the Schumock and Thornton criteria [16]. These assessments help prioritize cases requiring immediate intervention.

Management Strategies

Management includes immediate withdrawal of the suspected drug, symptomatic treatment, substitution with safer alternatives, and monitoring of outcomes [17]. Clinical pharmacists play an essential role in recommending therapeutic modifications and follow-up care.

CHALLENGES IN PHARMACOVIGILANCE

Despite the importance of pharmacovigilance, underreporting remains a major challenge worldwide [18]. Contributing factors include lack of awareness, inadequate training, and fear of legal consequences among healthcare professionals [19]. Furthermore, data integration and feedback systems in many healthcare institutions are insufficient [20].

FUTURE PERSPECTIVES

Digital health technologies such as electronic health records (EHRs), artificial intelligence (AI), and mobile apps are revolutionizing pharmacovigilance practices [21]. Clinical pharmacists must adapt to these innovations to improve data accuracy, early detection of signals, and patient-centered care [22].

Conclusion

Pharmacovigilance is essential for ensuring safe and effective use of medicines. Clinical pharmacists play a pivotal role in detecting, assessing, managing, and preventing ADRs. Their involvement enhances patient safety, promotes rational drug use, and strengthens healthcare systems. To maximize their contribution, structured training programs, supportive policies, and efficient reporting mechanisms are vital.

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Both authors are contributed equally

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