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Clinical Pharmacists' Contribution to Pharmacovigilance and Complementing Rationality

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Abstract

Pharmacovigilance is defined by the World Health Organization (WHO) as "the research and practises connected to the detection, evaluation, understanding, and prevention of adverse effects or other potential drug-related issues." As an integral element of the system, pharmacovigilance plays a crucial role in assuring patients' medication safety. Adverse Medication Reaction (ADR) is defined by WHO as any adverse and unanticipated response to a drug that occurs at levels commonly used in man for disease prevention, diagnosis, or therapy, or the alteration of physiological function.

Pharmacovigilance could identify complete information on unexpected and serious adverse events by evaluating medication impact. Due to time constraints and other variables, it would be impossible to discover all pharmacological effects during an in-vivo clinical study. Pharmacists perform more than just formulating and delivering medications. They play an incalculable significance in the pharmaceutical sector and clinical research. The practise of pharmacy extended well beyond community service. Pharmacist plays a paramount role in pharmacovigilance. Their position in pharmacovigilance differs by nation, but their primary purpose is to serve for the community's safety. Pharmacists may build a trusted environment by advising patients, eliminating prescription mistakes, and improving the patient's safety and quality of life.

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

INTRODUCTION

Pharmacovigilance is the science of detecting, assessing, comprehending, and preventing adverse effects or other potential drug-related problems [1], such as prescription mistake, overdose, underdosage, and so on. It is critical in guaranteeing medication safety and protecting patients by delivering high-quality medical treatment. It is a critical instrument for assessing the efficacy of medication therapy. Pharmacovigilance is acknowledged as a clinical specialty since it acts as a barometer for clinical care delivery in the country [2, 3].

Following the thalidomide disaster (phocomelia in kids whose mothers took thalidomide during pregnancy), WHO developed the pharmacovigilance system in 1968. According to the World Health Organization, an adverse drug reaction (ADR) is any unpleasant and undesired response to a medication that occurs at dosages commonly used in man for disease prevention, diagnosis, or treatment, or the alteration of physiological function. The WHO Collaborating Centre for International Drug Monitoring is the Uppsala Monitoring Center (UMC). UMC functions by collecting, analysing, and distributing information and national initiatives from member nations about medication improvement, toxicity, efficacy, and hazards. The effectiveness of the Pharmacovigilance programme is heavily reliant on the involvement of all health care providers, as well as excellent collaboration and communication between practitioners and the pharmacovigilance centre [4]. Reporting ADRs is seen as an active step toward maintaining and achieving safe medication treatment [5].

Pre-marketing clinical trials have proven to be unfavourable due to the small sample size, lack of long-term exposure to the targeted chemical, the presence of co-morbid disorders, demographic diversity, and concurrent use of other drugs. These aspects are to blame for a lack of understanding of the experimental molecule's effectiveness and drug-drug and drug-food interactions. Although pre-marketing clinical trials are important in assessing drug product safety and efficacy, they have limitations. Post-marketing monitoring and continuing Pharmacovigilance activities are essential actions used to monitor the effects of the

drug and ensure the safe use of the treatment [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]. TheNational Pharmacovigilance system is the main route to collect information on ADRs occurrences in both hospital and community settings [6].

ROLES OF PHARMACIST

On the professional level, the work of a pharmacist has evolved well beyond just producing or delivering pharmaceuticals to become more patient-centric [4]. Pharmacists contribute to medication safety by avoiding, recognising, recording, and reporting adverse drug reactions (ADRs) [5]. The function of the pharmacist in the department of pharmacovigilance differs per country, but their professional obligation stays the same regardless of jurisdiction [7]. A pharmacist has the ability to report ADRs on their own, however his/her clinical expertise may differ from that of a physician [2]. When effective risk information is provided back to health-care personnel, the process of Pharmacovigilance programme can be successful. The first essential step in preventing ADRs is to familiarise all healthcare practitioners with the risk-benefit profile of pharmaceuticals. 4 A pharmacist is critical in medication therapy monitoring [4]. Pharmacists can be deployed to help oversee the safe and effective use of available drugs, which includes ADR management. The pharmacist's valuable knowledge gathered during Pharmacovigilance should be valued [8].

Pharmacists serve as an open arm to clinical knowledge by providing resources such as databases. Pharmacists play an important role in generating communication materials such as newsletters and other publications that are used by other professions and professionals to disseminate medication warnings and other drug safety information that aids in the provision of

reasonable therapy. 9 Pharmacists must also participate in the collecting of data that may be beneficial in initiating longitudinal Pharmacoepidemiological research. 5 Pharmacists may provide a favourable atmosphere for patients by reducing medication mistakes, enhancing patient safety, and improving quality of life during counselling sessions [9,10].

In a research conducted by Mohmoud et al., 23 percent of the pharmacists engaged in the study were familiar with the ADR reporting process, but 77 percent had never reported ADRs. The main cause for not reporting ADRs is a lack of knowledge about the reporting mechanism [11]. Aside from reporting ADRs, pharmacists may also maintain track of crucial files and papers connected to patient safety by optimising the benefit and limiting the danger of pharmaceutical usage, as well as by staying up to date on newer drug innovations, regimens, and surgical procedures. A pharmacist should be well-versed in monitoring and educating patients on the use of over-the-counter drugs [7].

CONCLUSION

As part of their pharmacy profession, clinical pharmacists perform a critical role in managing medication prescriptions. They recommend sensible therapy to health care practitioners by offering data on adverse medication responses and drug-related concerns. Communication with the health care team helps to guarantee sensible therapy by improving the patient's quality of life. Pharmacists can improve the health environment in hospitals and increase their position by doing research on pharmacovigilance in more clinically valuable output. By implementing educational training programmes and seminars, the general public may be educated on how to reduce medication side effects and report ADRs. Pharmacists may build a trusted atmosphere by counselling patients on both drug-related and disease-related issues, as well as lifestyle changes. Pharmacists will be able to achieve new milestones in the future if their medication knowledge is constantly improved.

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