Journal of Pharmacovigilance
ISSN: 2329-6887

Rajanandh et al., J Pharmacovigil 2016, 4:6
DOI: 10.4172/2329-6887.1000221

Mini Review Open Access

Roles of Pharmacist in Pharmacovigilance: A Need of the Hour

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Received date: October 31, 2016; **Accepted date:** November 28, 2016; **Published date:** December 02, 2016

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. Adverse Drug Reaction (ADR) is defined according to WHO 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 finding through the Pharmacovigilance. It could not be done through clinical trials which are conducted in *in-vivo* method. Pharmacists are not mere preparing or dispensing of drugs. The professional practice reaches far beyond serving community. Pharmacists have an important responsibility in monitoring the on-going safety of medicines as part of their professional practice. Pharmacist role in pharmacovigilance varies from country to country, but the professional responsibility is the same regardless of jurisdiction. Pharmacists can create a trusted environment by counselling patients to reduce medication errors, improve safety and quality of care.

Keywords: Pharmacovigilance; Pharmacist; Adverse Drug Reactions (ADR); Prophylaxis

Introduction

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 [1]. Pharmacovigilance plays an important role in ensuring patients drug safety and providing high quality medical care and is an essential tool for the effective use of drug therapy. Pharmacovigilance is recognized as a clinical discipline and 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 of 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 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 healthcare professionals and their effective co-operation and communication between the practitioners and pharmacovigilance centre [4]. Reporting of ADRs is considered to be 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, 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 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 step to monitor effects of 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 nation-wide program as Pharmacovigilance Program of India (PvPI) in 2010. The program is being coordinated as a National Coordinating Centre (NCC), supervised under, The Central Drugs Standard Control Organization (CDSCO), 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 way to collect information about 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 community from not mere preparing or dispensing of drugs but has become more patient-centric [4]. Pharmacists contribute to the drug safety by preventing, identifying, documenting, and reporting of ADRs [5].

The role of pharmacist in the department of pharmacovigilance varies with 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 [4].

Pharmacist plays a vital role in medication safety 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 Pharmacovigilance should be appreciated [8].

Pharmacist act as an open-arm to clinical expertise in sharing of resources including databases. Pharmacist plays an essential role in developing communication materials like newsletters and other publications through the drug information and poison centres, which are utilized by different professions and professionals for disseminating drug alerts and other drug safety information [9].

Pharmacist must also, be involved in collection of data that might be useful in triggering the initiation of longitudinal Pharmaco-epidemiological studies [5]. Pharmacists can assure a positive environment to the patients in minimizing the medication errors, improve 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 ADRs is due to lack of awareness about the method of reporting [11].

Apart from reporting ADRs, pharmacist can also pre-occupy themselves in keeping track of important files and documents related to patient safety in maximizing the benefit and minimizing the risk of medication use, update his knowledge regarding newer drug inventions, regimens and surgical procedures. Pharmacist should have a firm knowledge in monitoring and providing counselling about the use of over-the-counter medications [7].

Conclusion

Research in pharmacovigilance will strengthen the clinical pharmacist's role in more clinically valued output. Educational training programs and workshops can clarify and enhance the knowledge of ADR reporting and how causality assessment of ADR is done. This will enable the pharmacists to play a prominent role in reporting ADRs and patient safety in the future.

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