

Pharmacovigilance: Clinical Perspectives towards Patient Safety

Gamal Osman Elhassan^{1,2*}

¹Unaizah College of Pharmacy, Qassim University, Qassim, Kingdom of Saudi Arabia

²Faculty of Pharmacy, Omdruman Islamic University, Khartoum, Sudan

*Corresponding Author: Gamal Osman Elhassan, Unaizah College of Pharmacy, Qassim University, Qassim KSA, Tel+966530965955; E-mail: go.osman@qu.edu.sa, gamaosma63@yahoo.com

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Abstract

Pharmacovigilance is an important and integral part of clinical research relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term adverse effects of medicines. Adverse drug reaction means all the noxious and unintended responses that occur after the administration of the drug at any dose in patients which may be related to the drug. The science and activities used for systematically identifying and correlating drugs and side-effects and taking corrective actions fall under the discipline of Pharmacovigilance. Its main aim is to minimize the risk related to drug use and to maximize their benefits. According to the regulations of worldwide health agencies, pharmacovigilance units collect adverse events from all over the world that were caused or might have been caused by the use of a specific drug. The aim of this review is to provide a summary of methods used in pharmacovigilance to guarantee the safety, drug, development and future need of pharmacovigilance in clinical practice.

Keywords: Pharmacovigilance; Adverse effects; Drug safety; Drug regulation

Introduction

The awareness about the adverse drug reactions in emergence of the practice of pharmacovigilance, which can be defined as the science of detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems [1-2]. It is widely accepted that a drug has to go through phases of clinical trial to establish its safety and efficacy before it is marketed. However, clinical trial offers various limitations, as it excludes some population groups such as children, pregnant women, and old age population are not studied during the trials. Moreover some other factors causing adverse drug reactions such as genetic factors, environmental factors, and drug-drug interactions may not have been studied during the clinical trial [3].

Medicines have changed the life by controlling and managing the diseases Besides their tremendous benefits, ample evidence continue to mount regarding adverse drug reaction such as they may cause illness, disability and even death, when taken for illness. . Adverse drug reactions (ADRs) rank top 10 leading causes of mortality. Aside from the intrinsic dangers associated with the products themselves, individual. Patients may exhibit particular and unpredictable sensitivities to certain medicines. The selection and use of the best and safest medicines for a given individual out of the many choices available, thus requires considerable skills on behalf of the prescribing practitioner [4].

Aim and Objectives of Pharmacovigilance

- Detection of severe and unexpected adverse drug reactions to the established drugs and even the minor ones to newer drugs [5].
- Identification of the risk factors associated with the development of adverse drug reactions and mechanisms of their causation like Type A, Type B, Type C, etc. [6].
- Quantitative estimation of the risk factors, incidence, and prevalence of adverse drug reactions. Estimation of the pharmaco-economic data related to ADRs [7].
- Improvement of patient care and safety in relation to the use of medicines with medical and paramedical interventions remains to be an important parameter, clinical training in pharmacovigilance and effective communication to the generic public [8].

Good Pharmacovigilance Practices

Risk assessment and risk minimization form what FDA calls risk management. It is an iterative process of:

- Assessing a product's benefit-risk balance
- Developing and implementing tools to minimize its risks
- Evaluating tool effectiveness and reassessing the benefit-risk balance
- Making adjustments as appropriate to the risk minimization tools to further improve the benefit-risk balance.

This four part process should be continuous throughout a product's lifecycle with the results of risk assessment informing the sponsor's decisions regarding risk minimization.

The Federal Food Drug and Cosmetic Act (FDCA) and FDA implementing regulations establish requirements for routine risk assessment and risk minimization (e.g., FDA requirements for professional labelling and adverse event monitoring and reporting) [9].

Pharmacovigilance and Pharmacoepidemiology in Risk Management

Risk assessment during product development should be conducted in a thorough and rigorous manner; however, it is impossible to identify all safety concerns during clinical trials. Pharmacovigilance involves the identification and evaluation of safety signals. Signals can arise from post marketing surveillance data and other sources, such as preclinical data and events associated with other products in the same pharmacological categories. It is possible that even a single well documented case report can be viewed as a signal, particularly if the report describes a positive challenge or if the event is extremely rare in the absence of drug use. Signals generally indicate the need for further

investigation, which may or may not lead to the conclusion that the product caused the event. After a signal is identified, it should be further assessed to determine whether it represents a potential safety risk and whether other action should be taken [10]

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