

## Chapter 20

# Pharmacovigilance: Basic Concepts and Applications of Pharmaco-informatics

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### ABSTRACT

*Any substance that is capable of producing a therapeutic effect can also produce unwanted or adverse effects. It is important to understand the basic concepts related to Adverse Drug Reactions (ADRs): epidemiology, classification, predisposing factors, evaluation parameters, and surveillance methods. Pharmacovigilance is defined as the science and activities relating to the detection, evaluation, understanding, and prevention of ADRs or any other drug-related problems. It involves patients, medical professionals, the pharmaceutical industry, drug regulatory agencies, and academic scientists. Pharmaco-informatics, the application of information technology with regard to the drug design, development, and drug use has played a major role in the appropriate implementation of pharmacovigilance at industry, regulatory, and hospital levels. The functioning of international regulatory agencies and drug safety departments of pharmaceutical industries has been greatly influenced by pharmaco-informatics. Pharmaco-informatics has changed the way in which health care is practiced. Modern information technology can be used by health care professionals for various purposes and, thereby, make a substantial contribution to optimize the quality of medication use in institutions with due importance of safety. Pharmaco-informatics has a major influence in the development of pharmacogenetics and its individual applications including improving drug safety. Pharmaco-informatics will play a major role in the future development and practice of pharmacovigilance. The present chapter is aimed at providing the readers an insight into the importance and basic concepts of pharmacovigilance, and the process involved in it. Application of pharmaco-informatics in improving drug safety at various levels from an industry, regulatory and hospital perspective is discussed.*

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## **INTRODUCTION**

*Primum non nocere* ('first of all be sure you do no harm') Hippocrates (460–370 BC)

Even though it is a long-held principle in medicine, it has never been completely achieved. Historically, there are many ways in which patients have come to harm through the practice of medicine including drug treatment, and this unfortunately continues in the present day. Adverse Drug Reactions (ADRs), a major cause of iatrogenic disease, are as old as Medicine itself (Routledge, 1998; Pirmohamed, 1998). Modern medicine has been blessed with a pharmaceutical armamentarium that is much more powerful than before. Although this has given health care providers the ability to provide better medical care for their patients, it has also resulted in the ability to do much greater harm (Storm, 2005).

Any substance that is capable of producing a therapeutic effect can also produce unwanted or adverse effects (Edwards, 2000). The World Health Organisation (WHO)'s definition of an ADR, which has been in use for about 30 years, is "a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function" (WHO, 1972).

ADRs remain an important concern in drug development as well as clinical use (Locatelli, 2009). However, ADRs may cause a significant burden to the health care system, as it is a major cause of patient morbidity and mortality. Furthermore, ADRs are known to increase the health care costs (Rodríguez-Monguio, 2003). Drugs are withdrawn from the market because of their unacceptable safety profiles. Over the last 25 years, approximately 10% of new drugs that were approved in the USA either had to be withdrawn or were labelled with a 'Black Box' warning (Pirmohamed, 2003).

Monitoring and identifying the adverse effects of drugs is important to ensure its safe use. Patient safety is important for any healthcare programme as it directly influences the overall benefits and acceptability of the programme (Kshirsagar, 2010). Even though the safety of drugs is evaluated during premarketing clinical trials, they have intrinsic limitations with respect to their ability to detect adverse events. Post marketing surveillance is concerned with the collection of data about drugs (or any other medical product) once they are marketed and thus available to the general population. (CDER, 1996). Pharmacovigilance is a broader term which is defined as the science and activities relating to the detection, evaluation, understanding and prevention of ADRs or any other drug-related problems (Mann, 2005). Pharmacovigilance is one among the major activities of any drug regulatory bodies throughout the world. The aim of pharmacovigilance is early detection and assessment of new ADRs and subsequent introduction of risk minimization and preventive measures (Stenver, 2008). It involves patients, medical professionals, the pharmaceutical industry, drug regulatory agencies, and academic scientists. Pharmacovigilance has constantly grown in importance in last 10 years (Locatelli, 2009).

Information technology has played a major role in the advent of pharmacovigilance activities at industry, regulatory, and hospital level. Pharmacoinformatics, the application of information technology with regard to the drug design, development, and drug use has played a major role in the appropriate implementation of pharmacovigilance at various areas. It influences the monitoring, identification and reporting of drug safety at hospitals. Drug safety activities at the industry and regulatory sector are greatly facilitated by the information technology in generation of drug safety signals, reporting of ADRs, maintaining and evaluation of ADRs reports (Storm, 2005).

The present chapter is aimed at providing the readers an insight into the importance and basic concepts of pharmacovigilance, and the process

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