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Current Trends in Pharmacovigilance

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The rapid and continuous progress of medical and pharmaceutical sciences has resulted in the availability of modern medicines that can efficiently prevent, control and/or manage disease states. Despite a plethora of benefits, adverse reactions to medicines are not uncommon and are associated with most newly developed drugs. The adverse effects range from milder side-effects to severe hypersensitivities and often result in new illness, disabilities and death. Adverse drug reactions of medicines have increased in prevalence over the years; and in many countries they rank among the major causes of mortalities.

It is thus imperative to have a well-organized system to continuously monitor and assess the safety of medicines. Pharmacovigilance is such a system. The concept of pharmacovigilance is not new and its origins date back over 50 years. The thalidomide tragedy of 1961 drew attention to the importance of the assessment of the adverse effects of drugs. Between 1965 and 1970, after several meetings and resolutions, the International Drug Monitoring Program was formed by the World Health Assembly. Pharmacovigilance is defined by the World Health Organization (WHO) 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 a multi-modal role in promoting and improving public health. The key goals of pharmacovigilance are:

- To identify the risks associated with use of medicines by the patients.
- To participate in comparative assessment of potential beneficial and adverse effects of the drugs and help optimize the nature of use.
- To promote safe, effective and rational use of medicines.
- To promote awareness among patients and general public regarding the safe use of medicines via effective communication.

These goals are achieved only with the collaborative efforts and contributions from the key partners in the area of pharmacovigilance. Inputs from a variety of sources such as government, academia, pharmaceutical and medical associations, health professionals and the media will help towards achieving improved management of risks associated with the use of medicines.

Pharmacovigilance is ingrained, and rightly so, in several areas of healthcare management of general population. The key areas where pharmacovigilance is incorporated are, *National Drug Policy*: For most nations, the first step to ensure safe and rational use of medicine is the establishment of drug regulatory bodies with dedicated pharmacovigilance programs to monitor and assess the adverse drug reactions and communicate finding to relevant stakeholders. *Drug regulation*: The scope of drug regulatory authorities is beyond just the approval of manufacture and marketing of new medicines. Working in close collaboration with pharmacovigilance programs, these regulatory authorities ensure continual safety of the drugs in public domain by conducting post-marketing surveillance and analysis of the benefits and harmful effects of the drugs in a broader population. *Clinical practice*: An efficient exchange of information between the pharmacovigilance centres and professionals in clinical practice is vital to maintaining a high quality healthcare. Pharmacovigilance programs in clinical practice helps health care professionals to continuously update and remain current on the knowledge base related to adverse outcomes of medicines. *Public health programs*: Several underdeveloped nations lack a well-organized healthcare infrastructure. Such countries have high prevalence of a multitude of tropical infectious diseases; most of them existing concurrently in a population. Simultaneous administration of several medicines to such population is often carried out without regards to or knowledge of the adverse drug reactions or drug interactions. Pharmacovigilance programs in such situations provide adequate training to the healthcare delivery professionals and helps improve general awareness regarding the safe use of medicines.

Several national and international bodies provide information and guidelines for proper implementation of pharmacovigilance programs. These agencies are excellent resources for information on the management of risks associated with the use of medicines. World Health Organization (WHO) provides a comprehensive database of information on the adequate implementation of pharmacovigilance as an important tool to ensure the safety of medicine in public health. The United States Food and Drug Administration (USFDA) published guidelines for the pharmaceutical industry regarding Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment of marketed drugs in 2005. Despite being great resources, the access to the information from these sources is limited to a small segment of the society. There is a widely perceived need of a platform where the latest and relevant information in the form of scientific findings, regulations, reviews and guidelines on the safe use of medicines is readily available to all sections of populace is available.

The Journal of Pharmacovigilance is an exact step in this direction. This publication aims to collect and disseminate the scientific information on a broad array of unintended drug effects including side effects, adverse drug reactions, drug interactions, short and long term toxicities etc. This Journal is an open access peer reviewed journal, thus making all the published information immediately and freely available to the public.

As we begin this journey, I welcome the members of academia, industry, government and others in the healthcare community to actively participate and contribute their opinions, scientific findings and expert reviews to The Journal of Pharmacovigilance. I firmly believe that this journal will have a strong and a positive impact in improving the public awareness related to detection, assessment, understanding and prevention of adverse effects of medicines.

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