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Challenges of Pharmacovigilance

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Abstract

The occasion of an adverse event is not forever throughout appointment to the Healthcare Center. It can occur after several hours of administering the drug. Patients fail to remember all the relevant information about adverse events and are not able to report it accurately. Patients are anxious and report all their discomfort as adverse events. Adverse drug events (ADE) reported are not always serious and may be symptoms of a disease. Other incidents where a patient has not followed instructions during medication or patient has had side effects caused by concomitant medicines taken along with the study drug could be reported as adverse events. Such wrong reporting can lead the drug safety committees to incorrect conclusions which in turn lead to the suspension or withdrawal of drugs. Pharmacovigilance is observed as the regular process of knowing the secure use of pharmaceutical products and assists in reducing the risk of any harm that may come to patients. Most of Pharma Companies have to perform a comprehensive drug safety and pharmacovigilance audit to assess their compliance with worldwide laws, regulations, and FDA guidance.

Key-Words: ADR, ADE, Concomitant

Introduction

Pharmacovigilance focuses on drug quality, medication errors and adverse drug reactions which impact the health care system by affecting a significant patient population.WHO defines pharmacovigilance as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine-related problem". Ultimately, pharmacovigilance is regarded as the constant process of identifying the safe use of pharmaceutical products and helps in minimizing the risk of any harm that may come to patients. Pharma Companies must conduct a comprehensive drug safety and pharmacovigilance audit to assess their compliance with worldwide laws, regulations, and FDA guidance. Below are a few challenges to Pharmacovigilance.

Major Challenges:

Engaging the Public:

The adverse event reporting has to get initiated from the public and that's why it become a challenge to make people aware about what and why of pharmacovigilance. As per FDA estimates, not even 10% of all adverse events get actually reported!

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Handling and Managing the Informatics:
The biggest challenge lies in collecting, reviewing, and reporting of patient safety information. A less-expert or novice Contract Research company may not be able to fulfill the client's expectations owing to the challenge of full-spectrum monitoring of a drug. Communication from consumers is crucial in determining the cause and flow of information for Adverse Event Reports; the challenge hers is to extract accurate and relevant pharmacovigilance data from consumers.

Benefit-risk Assessment:
The changing times have brought a transition in the way Pharmacovigilance is perceived. It is no more reporting about the frequency of adverse events; rather now it is presenting a complete picture of Benefit-Risk assessment of a drug or biologic.

Poor Healthcare Delivery System:
Pharmacovigilance facing the challenges in healthcare delivery because of not getting priority. Biasness of drug in healthcare delivery system is also a big issue. Poor standard, poor funding and mostly political pressures creating barrier in implementing of pharmacovigilanceprogramme. Other challenges are associated with health professionals are few in number but many prescriber. Drug safety not covered well in medical training. Health professionals are now days too busy so motivation is too low. Lack of continuing medical education and difficult in availability of drug information is another big issue. Some drug use problems contributing to the barriers in pharmacovigilanceprogramme of India are availability of many types of drugs in households and dispensing the drugs by untrained persons. Some other drug use problems are wide spread use of injections, high levels of antibiotic use, inadequate treatment guidelines, poor prescribing and dispensing practices, counterfeit drugs and using of traditional medicines. Confounding illness is also a very big factor in current scenario. Diseases like tuberculosis, HIV/AIDS, malnutrition requires multiple drug therapy and adverse event occurs due to drug interactions and can lead to severe health hazard.

Self-Medication:
Self-medication is one of the problems in our country as people are not educated about drugs and they take drugs prescribed by pharmacist without proper prescription. Advertisements by the drug companies and the readily available drug over-the-counter with available pamphlets about the dose, indication, side-effects make the patients to take their own therapeutic decisions, without assistance from doctor or pharmacist. This leads to unknown adverse effects which usually goes unreported and may have bad impact on the society.

Traditional Medicines
Traditional drugs are considered safe with few side effects. The processing of natural drugs are not done properly, toxic and essential ingredients are not known most of the time, they are given for long duration and there is lack of knowledge between interaction of herbal drugs with modern medicines. Lack of knowledge regarding adverse drug profile of drugs poses a challenge to pharmacovigilance.

Conclusion
Pharmacovigilance continues to play a crucial role in meeting the challenges posed by the increasing medicine in the market and lack of professional in the health sector. It should operate for development of scientific culture. Thus, it require inputs from various fields like sound academic base, basic training of pharmacovigilance and skills to deal with it. Analysis of pharmacovigilance data should be processed and published to form the basis for the prevalence and incidence of adverse drugs reaction of various drugs. If unknown adverse effects and toxicity appear, it should be made essential for the health professional or pharmacovigilance expert to report, analyze and communicate effectively to the audience to interpret the information. Adverse effects can be minimized by having sound knowledge about the side effects of the drugs. The improve communication regarding pharmacovigilance between the health professionals and the public as well as to educate health professionals regarding pharmacovigilance would help to understand the effectiveness or risk of medicines that they prescribe and improve the unwanted risk to the patient.

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