



Recent Advancements In Pharmacovigilance

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Introduction

According to W.H.O the science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug related problems.

Mainly the pharmacovigilance came into existence after the thalidomide effect 1960. more than 46 countries are marketed the thalidomide. it shows side effects like nausea mainly in the pregnancy mothers. the reports says that more than 20,000 infants are born deformedly.

Its main aim is to improve patient care and safety in relation to the use of medicines and all medical and paramedical inventions. To improve public health in relation to the use of medicine. To promote understanding education and clinical training in pharmacovigilance and its effective communication to the health professionals and the public.

There are 2 types of process:

1. Spontaneous reporting
2. Mandatory reporting.

Spontaneous reporting

Most common form of ADR reporting. Health care professionals identify and report any suspected adverse reaction to their national pharmacovigilance or to the manufactures.

Mandatory reporting

Manufactures are requested to submit their reports to the national authority in the form of periodic safety update report.

Pharmacovigilance is now firmly based on sound scientific principles and is integral to effective clinical practice. The discipline needs to develop further to meet public expectations and the demands of modern public health.

Clinical trial regulation: In recent years there has been a substantial increase in the number of clinical trials in developed and developing countries. In their approval of clinical trials, regulatory bodies look at safety and efficacy of new products under investigation.

Post marketing safety drug monitoring: These includes detection of drug interactions, measuring the environmental burden of medicines used in large populations, assessing the contribution of 'inactive' ingredients to the safety profile, systems for comparing safety profiles of similar medicines, surveillance of the adverse effects on human health of drug residues in animals, e.g. antibiotics and hormones.

Pharmacovigilance in national drug Policy: The provision of good quality, safe and effective medicines and their appropriate use is the responsibility of national governments.

Pharmacovigilance in Disease Control Public Health Programme: The monitoring of medicine safety in countries where there is no regulatory or safety monitoring system in place, or in remote areas with little or no health care surveillance or infrastructure, has been identified as a matter for concern.

The Uppsala Monitoring Centre (UMC) is the operational center of the WHO Programme for International Drug Monitoring, which currently includes a network of national pharmacovigilance centers in approximately 150 countries, representing 95% of the global population.

The development of new and effective medicinal products makes a positive contribution to the health and well-being of individuals. However, there is a need to improve pharmacovigilance (PV) systems to more effectively monitor and take action on safety issues associated with medicines to enhance their contribution to public health.

Factors behind the development of current trends

- Globalization of the pharmaceutical market.
- Development of innovative products.
- Increasing public awareness and changing expectation with regards to the safety of medicines.
- Large costs associated with drug safety.

By incorporating PV, we will be able to prepare the medicines with good efficacy, safety quality and minimum harmful effect.

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