



A Review: Pharmacovigilance Is A Master Key For Drug Safety Monitoring And Its Importance

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Abstract

Pharmacovigilance is like a sunshade to describe the processes for monitoring and evaluating ADRs and it is a key component of effective drug regulation systems, clinical practice and public health programmes. The number of Adverse Drug Reactions (ADRs) reported resulted in an increase in the volume of data handled, and to understand the pharmacovigilance, a high level of expertise is required to rapidly detect drug risks as well as to defend the product against an inappropriate removal. The current global network of pharmacovigilance centers, coordinated by the Uppsala Monitoring Centre, would be strengthened by an independent system of review. This would consider litigious and important drug safety issues that have the potential to affect public health adversely beyond national boundaries. Recently, pharmacovigilance has been confined, mainly to detect adverse drug events that were previously either unknown or poorly understood. Pharmacovigilance is an important and integral part of clinical research and these days it is growing in many countries. Today many pharmacovigilance centers are working for drug safety monitoring in this global pitch, however, at the turn of the millennium pharmacovigilance faces major challenges in aspect of better safety and monitoring of drugs. In this review we will discuss about drug safety, worldwide

pharmacovigilance centers and their role, benefits and challenges of pharmacovigilance and its future consideration in healthcare sectors.

Keywords: Drug safety, erice declaration, pharmacovigilance

Introduction

Drug safety and pharmacovigilance remains a dynamic clinical and scientific discipline. 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 drug-related problem';^[1] it plays a vital role in ensuring that doctors, together with the patient, have enough information to make a decision when it comes to choosing a drug for treatment.^[2] However, despite all their benefits, evidence continues to get those bigger adverse reactions to medicines which are common, yet often preventable, cause of illness, disability and even death. In some countries, adverse drug reactions (ADRs) rank among the top 10 leading causes of mortality. In order to prevent or to reduce harm to patients and thus improve public health, mechanisms for evaluating and monitoring the safety of medicines in clinical use are vital.^[1] Pharmacovigilance programs in the next 10 years, describe in brief the potential implications of such trends on the evolution of the science. These days pharmacovigilance is facing lots of challenges to develop better health care systems in this global pitch.^[3] Major challenges are globalization, web-based sales and information, broader safety concerns, public health versus pharmaceutical industry economic growth, monitoring of established products, developing and emerging countries, attitudes and perceptions to benefit and harm, outcomes and impact.^[4]

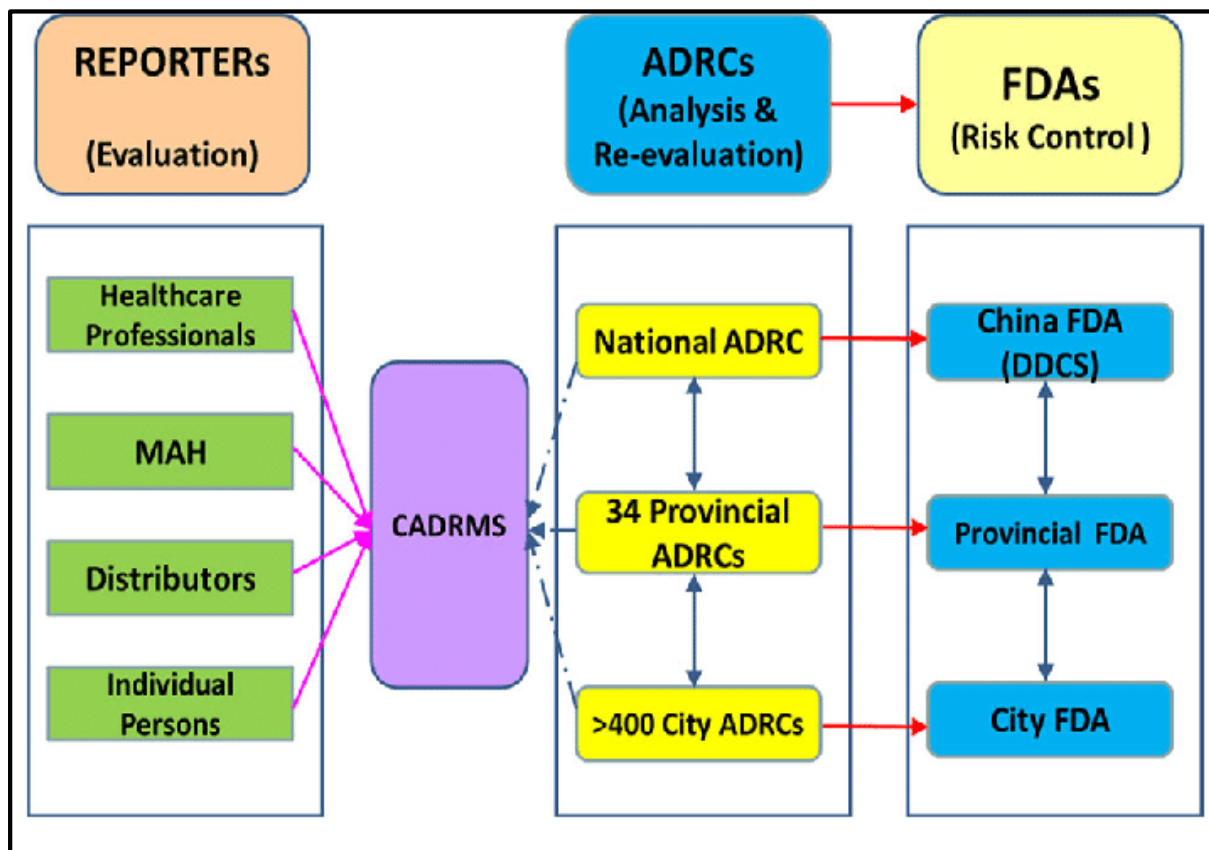
Historical perspectives of who- drug safety monitoring

In 2002, more than 65 countries have their own pharmacovigilance centers. Membership of the WHO for International Drug Monitoring is coordinated by the WHO Collaborating Centre for International Drug Monitoring, known as the Uppsala Monitoring Centre (UMC). Pharmacovigilance is now firmly based on sound scientific principles and is integral to effective clinical practice.^[5] The discipline needs to develop further to meet public expectations and the demands of modern public health. The Sixteenth World Health Assembly adopted a resolution (WHA 16.36) that reaffirmed the need for early action in regard to rapid dissemination of information on adverse drug reactions and led later to creation of the WHO Pilot Research

Project for International Drug Monitoring. The purpose of this was to develop a system, applicable internationally, for detecting previously unknown or poorly understood adverse effects of medicines. [6]

World wide soldiers of pharmacovigilance

A complex and vital relationship exists between wide ranges of partners in the practice of drug safety monitoring. These partners must jointly anticipate, understand and respond to the continually increasing demands and expectations of the public, health administrators, policy officials, politicians and health professionals.



The Quality Assurance and Safety:

The team is a part of the Department of Essential Drugs and Medicines Policy, within the WHO Health Technology and Pharmaceuticals cluster. The purpose of the department is to help save lives and improve health by closing the huge gap between the potential that essential drugs have to offer and the reality that for millions of people, particularly the poor and disadvantaged, medicines are unavailable, unaffordable, unsafe or improperly used. [7]

The Uppsala Monitoring Centre:

The principal function of the Uppsala Monitoring Centre is to manage the international database of ADR reports received from National Centers.^[8] The UMC has established standardized reporting by all National Centers and has facilitated communication between countries to promote rapid identification of signals.^[9]

The National Pharmacovigilance Centers:

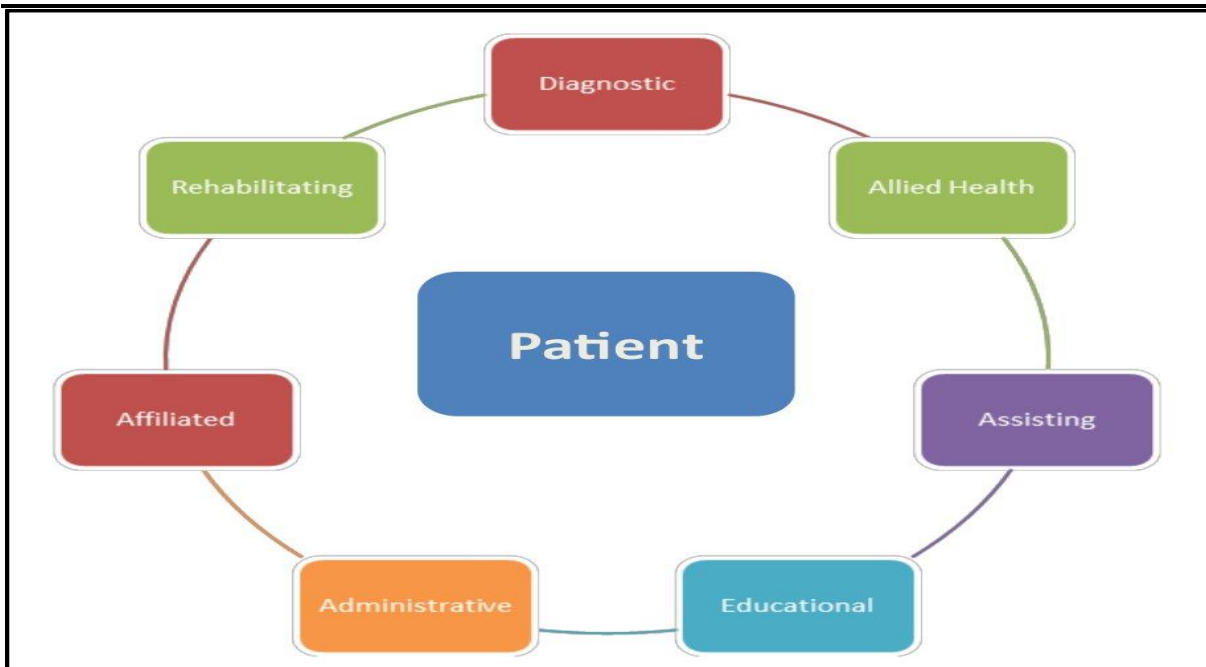
National Centers have played a significant role in increasing public awareness of drug safety. This development is partly attributable to the fact that many national and regional centers are housed within hospitals, medical schools or poison and drug information centers, rather than within the confines of a drug regulatory authority.^[10] Major centers in developed countries have established active surveillance programmes using record linkage and prescription event monitoring systems (PEM) to collect epidemiological information on adverse reactions to specific drugs. Such systems have already been implemented in New Zealand, the United Kingdom, Sweden and the United States of America. The entire cost of a pharmacovigilance system, compared with the national expenditure on medicines or the cost of ADRs to the nation is very small indeed.^[11]

Hospitals and Academia:

A number of medical institutions have developed adverse reaction and medication error close watch systems in their clinics, wards and emergency rooms. Case-control studies and other pharmacoepidemiological methods have increasingly been used to estimate the harm associated with medicines once they have been marketed.^[12] Academic centers of pharmacology and pharmacy have played an important role through teaching, training, research, policy development, clinical research, ethics committees (institutional review boards) and the clinical services they provide.^[13]

Health Professionals:

Originally physicians were the only professionals invited to report as judging whether disease or medicine causes a certain symptom by exercising the skill of differential diagnosis. Today, different categories of health professionals will observe different kinds of drug related problems.^[14]



Patients:

Only a patient knows the actual benefit and harm of a medicine taken. Direct patient participation in the reporting of drug related problems will increase the efficiency of the pharmacovigilance system and compensate for some of the shortcomings of systems based on reports from health professionals only. ^[15]

Pharmacovigilance in drug regulation

Pharmacovigilance programs made strong by links with regulators. Regulators understand that pharmacovigilance plays a specialized and pivotal role in ensuring ongoing safety of medicinal products. ^[16]

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. ^[17] Safety monitoring of medicines in common use should be an integral part of clinical practice. Education and training of health professionals in medicine safety, exchange of information between national pharmacovigilance centers, the coordination of such exchange, and the linking of clinical experience of medicine safety with research and health policy, all serve to enhance effective patient care. A regular flow and exchange of information in this way means that national pharmacovigilance programmes are ideally placed to identify gaps in our understanding of medicine-induced diseases. ^[18]

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. The Council for International Organizations of Medical Sciences (CIOMS) report on benefit-risk assessment of medicines after marketing has contributed to a more systematic approach to determining the merit of available medicines. ^[19]

Pharmacovigilance in national drug Policy:

The provision of good quality, safe and effective medicines and their appropriate use is the responsibility of national governments. Multidisciplinary collaboration is of great importance in particular, links need to be forged between various departments of the ministry of health and also with other stakeholders, ^[28,29] such as the pharmaceutical industry, universities, nongovernmental organizations (NGOs) and those professional associations having responsibility for education on rational use of medicines and pharmacotherapy monitoring. ^[20]

Pharmacovigilance in Disease Control Public Health Programmes:

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. ^[24,25,26] The problems are especially apparent in situations that involve the use of medicines in specific communities, for example, for the treatment of tropical diseases such as malaria, leishmaniasis and schistosomiasis, and for the treatment of HIV/AIDS and tuberculosis. Pharmacovigilance should be a priority for every country with a public health disease control programs.

^[21,22,23,27]

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