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Pharmacovigilance: Significance and challenges

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Abstract--The World Health Organization (WHO) defines Pharmacovigilance as the science & activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug related problem. The National Pharmacovigilance Programme (NPVP) was launched in 2004 with World Bank funding till 2009, which was renamed as Pharmacovigilance Programme of India (PvPI). With advancement in the field of science and technology, India is emerging as a hub for clinical trials and new drug development, which challenges the monitoring of safety concerns in the use of new drugs. It has been difficult to identify or track the adverse drug reactions (ADRs) that occur in the patients due to polypharmacy, use of over the counter (OTC) preparations, change in physician etc. Hence the national programme has gained importance in our country off late. Yet it is observed that the importance of this programme is not realized by all health care professionals. Therefore, to support & strengthen the national programme which aims to identify, report & analyze the identified ADRs, it would be essential to sensitize the health care professionals through various means & faculty development programmes.

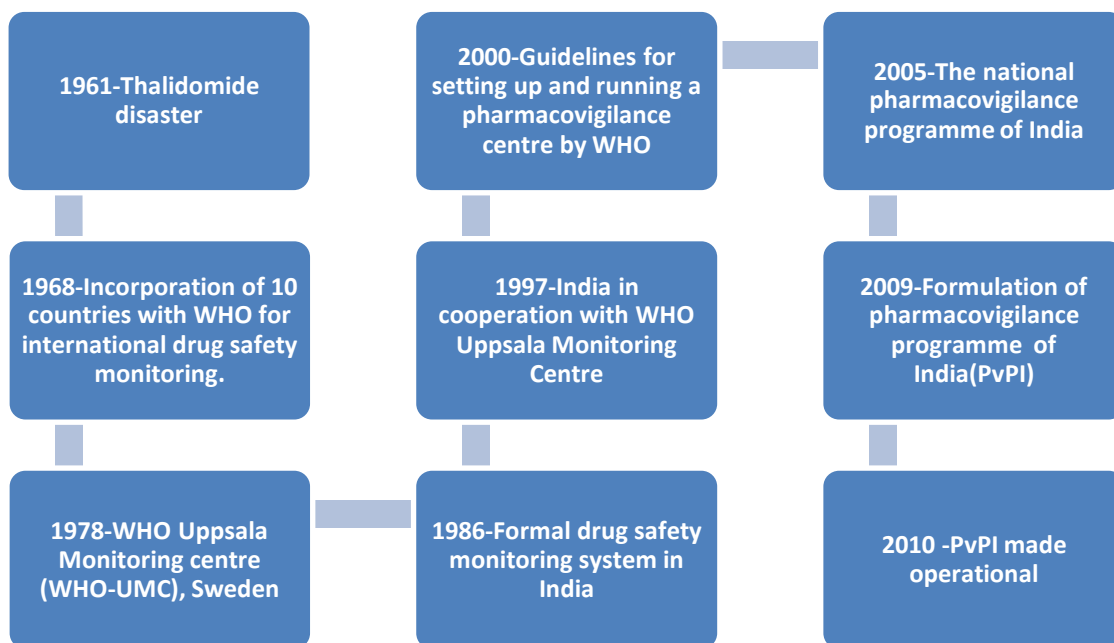
Keywords---Adverse Drug Reaction, CDSCO, National Pharmacovigilance Programme, OTC, Pharmacovigilance programme of India, WHO.

1. Introduction

As defined by WHO, Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems.[1] Pharmacovigilance is an important discipline, which deals with adverse drug reactions. Role of pharmacovigilance in

the health sector is to rationalize drug therapy for safety as well as educating people regarding the consequences of adverse drug effects. Adverse Drug Reactions is the fourth global leading cause of death. India is emerging as a hub for clinical trial in the world and many new drugs are being introduced in our country. So, there is a need for a vibrant pharmacovigilance system in the country. [2] Therefore, it is important to address various challenges of pharmacovigilance in order to deliver better health care to the people of our country.

2. Pharmacovigilance: Growth & Development [1]



3. Why Pharmacovigilance is necessary?

Apart from preclinical studies, clinical trials involve only smaller number and selected group of patients so, less common adverse drug reactions (ADR) are often identified at the time when a drug enters the market. The use of drugs in organ-impaired patients and use in special populations like pregnant women and children are not studied extensively in clinical trials because of ethical limitations. In order to launch the new products simultaneously in various countries the pharmaceutical companies put a larger population to risk of adverse effects. Use of new products by the physicians as well as the patients over the old standard ones has also caused more concern as most new drugs are used for improving the quality of life instead of the actual clinical condition thereby shifting the hospital based therapy to home base self administered therapy. The trend of converting the prescription only drugs to over the counter drugs (OTC) has reduced the involvement of physicians and pharmacists making the assessment and reporting of adverse drug reactions very difficult. The drugs are easily accessible using the internet. Besides the complimentary medicines are being used very popularly. A

number of studies conducted throughout the world have demonstrated that adverse drug reactions (ADRs) significantly decrease the quality of life, increase hospitalizations, prolong hospital stay and increase mortality and finally increase the economic burden to patients & society.[3] OTC drugs are used more widely by patients for self-medication, hence the general public is at risk of exposing itself to ADRs. So, Pharmacovigilance is necessary for promoting rational use of medicines and adherence.[4]

4. Challenges

Administration: Pharmacovigilance systems are not well funded and organized for a vast country like India to serve patients and the public.

Health Care Professionals: Among health care professionals, lack of awareness, understanding & lack of motivation lead to underreporting of adverse drug events. The information obtained at the zonal centers from various peripheral centers is often poor and not well-analyzed.. [5]

Self Medication: People take drugs prescribed by pharmacist without proper prescription. Advertisements by the drug companies and the readily available OTC drugs with available pamphlets about the dose, indication, side-effects make the patients to take their own therapeutic decisions, without assistance from doctor or pharmacist which leads to unknown ADR.[4]

Confounding illness & polypharmacy: Diseases like tuberculosis, HIV/AIDS, etc and critically ill patients receive polypharmacy. So, the adverse effects which occur due to interaction between different drugs cause a problem to identify the offending drug.

Clinical trial monitoring: India is emerging as a hub for clinical trial in the 21st century. In most of the clinical trials, adverse drug reactions that happen due to the test drugs go unreported and not informed to the regulatory authority due to personal interest or for the fear of litigation. Thus clinical trials pose a great challenge for pharmacovigilance programme. [5]

The problem of under-reporting is faced almost all over India. The reasons for under-reporting are non-availability of ADR forms, lack of awareness of its importance, practitioners find it not to be important, fear of risk litigation / feeling of shyness, fear of negative reflection of one's competence, difficulty in identifying the culprit drug, failure to understand what to report and failure to understand whom to report.

4. Future Prospects

Considering the challenges for pharmacovigilance in India, there is immense need for robust pharmacovigilance system, which may be achieved by following proposals like education and training of medical students, pharmacists and nurses and other healthcare professionals in the area of pharmacovigilance. To Make pharmacovigilance reporting mandatory and introducing pharmacovigilance inspections. Creating a clinical trial and post marketing database for serious

adverse event & ADRs for signal detection and access to all relevant data from various stakeholders. Strengthening the DCGI office with trained Scientific and medical assessors for Pharmacovigilance Building a network of pharmacovigilance and pharmacoepidemiologists in India.[7][8]

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