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A REVIEW ON: PHARMACOVIGILANCE

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ABSTRACT

Pharmacovigilance is an important and integral part of clinical research. Pharmacovigilance Is "defined as the pharmacological science relating to the detection, assessment, Understanding and prevention of adverse effects, particularly long term and short term Adverse effects of medicines. Here the main focus on the aims and role of pharmacovigilance In medicine, basic term involved in Pv. Pharmacovigilance Programme in India and their goals and national programme of Pharmacovigilance and centre in India. The important role played by health care professional, pharmaceutical industries, Media, and programmes carried by WHO. Their role in collecting the report of ADRs of medicine. further effectiveness and risk assessment of therapies are been discussed.

Keywords: *adverse drug reaction, pharmacovigilance, drug safety*

1. INTRODUCTION

Pharmacovigilance is an important and Integral part of clinical research .Drug have changed the way in which disease are treated.despite all the advantages of pharmacotherapy , adverse reactions are a recognised hazard of drug therapy . adverse drug reaction (ADRs) are a common , frequently, disability & death .the ADRs is may be defined as "an appreciably harmful or unpleasant reaction" resulting from an interference related to the use of a medical products, which predict hazard from future administration & require prevention or specific treatment or alteration in the dosage form or withdrawal of the product.(2)

Drug safety and pharmacovigilance (PV) remain a dynamic clinical & scientific discipline. in 1968 the WHO promoted the" programm for international drug monitoring" the project goal was identify the world data on ADRs . In perticular the main aim of "WHO programmed" was to identify the earliest possible Pv signal .the term Pv was proposed in the mid-70s by a French group of pharmacologist and toxicologist to define the activities promoting , assessment & risk of side effects related with the drug. According to WHO world health organization the pv define as " The science & activities relating to the detection, assessment, understanding and prevention of advers effect of drug or many other drug related problems " it plays a key role in make confirm that doctor , together with the patient have sufficient information to make a decision when it comes to select a drug for treatment .however, even though all their benefits evidence continues to get those bigger adverse reactions to medicine which are common, preventable causes of illness disability & even death .in some countries ADRs rank is among the top 10 leading cause of mortality. in order to prevent or to reduce harm to pateint and improve public health.(3)

The clinical research industry has grown around the world wide in past years .the main goal of pharmaceutical companies has to innovate new drug in market .the company has to perform clinical trials as per ICH GCp guidelines. Pv officially introduce in December 1961 was publication of case report in the Lancet by W.McBride ,the Australian doctor who first boosted a cause link between serious fetal deformaties (phocomelia) and thalidomide .was a drug used during a pregnancy for treatment as antiemetic and sedative agent in pregnant women. (4) is a main part of clinical research. both clinical trial Safety and post marketing Pv potential known as post marketing study or phase IV clinical trail .are critical throughout the product life cycle. in recently high no. of drug withdrawal both the pharmaceutical companies and various regulatory agencies across the globe have raised the bar. early detection of signal from post – marketing surveillance studies and clinical trials in early phase now been updated by major pharmaceutical companies in order to identify & understand the risk of side effects associated with their medicinal products or early as possible . (4) continues monitoring of drug effect ,side effects , contraindications which could result in a high degree of mortality, are essential to minimise risk .no degree of care and caution are the preclinical and clinical testing stages can ensure safety, a drug is marketed and prescribed to large population across the country and outside. because clinical trial involved thousands of patients at most ,less common side effects and ADRs are often unknown at the time a drug enter in to the market.

2. HISTORICAL BACKGROUND OF PV

The protection of drug became now no longer the early problem withinside the history Of drug. The thalidomide tragedy of Nineteen Sixties opened the eyes of Drug regulators in addition to different problem healthcare professionals To set up a manner to make certain drug protection. The mile stone withinside the Drug protection became the guide of chloroform associated death On The Lancet magazine for the primary time in 1893. Safety of drug Have become the world by wide problem and one-of-a-kind tasks had been taken with the aid of using one-of-a-kind international locations to guard public fitness and protection.

The US FDA act changed into exceeded in 1906 for the primary time, however it changed into amended To govern misbranding of components and fake marketing and marketing claims After 107 deaths with the aid of using using di-ethylene glycol as a solvent for Sulphanilamide elixir. There had been radical modifications withinside the drug Protection problems after the global thalidomide tragedy which changed into First suggested with the aid of using an Australian obstetrician, Dr. William McBride In December 1961.

He pronounced thalidomide related critical deadly deformities (phocomelia) utilized in pregnancy. This drug had now no longer been Thoroughly screened for teratogenicity, however comparable malformations Had been sooner or later proven withinside the rabbit and at excessive dose withinside the Rat. In West Germany 4000 people had been affected. The tragedy Made the arena to be extra challenge approximately the drug protection, As efficacy became most effective the parameter to look the impact of drugs. Immediately after the tragedy the United States FDA act became amended to Obligatory pre-advertising submission of each efficacy and Protection records in 1962.

LIST OF DEFINITION (4)

Adverse events – An adverse event is defined as any unfavorable and unintended response to a drug ,whether or not considered related to the product. Includes medical error (miscalculation, misadministration , difficulty in interpreting handwritten order , misunderstanding of verbal orders ,name confusion of drug and packaging or labelling of drug are thus not included in this definition) and adverse drug reactions .

Adverse drug reaction – is any noxious, unintended and undesired effect of a drug which occurs at a dose used in human for prophylaxis and diagnosis.

Post – marketing surveillance – (PMS) is a practice of monitoring the safety of a pharmaceutical drug or device after it has released in the market.

Clinical trial – clinical trial are a test in medical reaserch & drug development that generates safety & efficacy data for health intervention. Eg . Diagnostics, device, therapy protocol.

Pharmacology – study of the uses effect and mode of actions of drug

Pharmacovigilance – the science & activities relating to the detection, assessment, understanding and prevention of advers effect or any other drug related problems.

Side effects – any unintended effect of pharmaceutical product occuring at normal dosage which is related to the pharmacological properties of the drug

Adverse drug reactions – ADRs is an unwanted, undesirable effect of a medicine that occurs during usual clinical application.

Type A is called as Augmented Adverse Drug Reactions:

- These are augmented pharmacologic effects and are often predictable and dose Dependant.
- They are normal pharmacological dose-related effect of the drugs and likely to be Detected in clinical trials.
- They are largely avoidable with care.

E.g.: Postural hypotension in a patient on anti-hypertensive medication,

- Hypoglycemia with anti-diabetics
- Anticholinergics and dry mouth,
- Sedation with anti-histamines

Type B is known as Idiosyncratic or immunologic reactions

- They are rare and unpredictable, the effects are related to abnormal interaction between Patient and drug, it is-dose independent, unrelated to normal pharmacodynamics of the Drug and may have genetic basis.
- They are commonly reported in the post marketing surveillance

E.g. : Immunological like rash or anaphylactic reaction associated with Penicillin use

Table: 1) List of some suspected and known drug associated with adverse effects. (4)

Drug	Advers drug reaction
Thalidomide	Phocomelia , multiple defects
Methotrexate	Fetal death, multiple defects
Tetracycline	Discolored teeth , retarded bone growth
Warfarin	Nose, eyes & hand defects
Quinidine	Ringing in ear, growth retardation
Phenytoin	Various malformations
Rifampicin	Orange colour urine
Anti-cancer drug	Cleft palate, multiple defects
Progestin	Virilization of female fetus
Chloremphenicol	Grey baby syndrome

Aim of pharma covigilance:

PV plays a key role in determining the severity of pharmacological side effects, whether they are produced by oral, parenteral, or intravenous medicines. Before being marketed worldwide, some medications are subjected to ADR testing. PV plays an important role in the assessment, detection, and identification of medications that induce ADRs and the mechanism by which they do so. However, it is the obligation of the doctors involved in the case to meet these requirements of discovering and eradicating a side effect; nurses, health workers, residents, and proper patient supervision aid to ease the root cause of ADR.[9] The main goals of pharmacovigilance are to demonstrate the efficacy of drugs by tracking their adverse effect profile for many years from the lab to the pharmacy; improving public health and safety in relation to drug use; encouraging the safe, rational, and cost-effective use of drugs; promoting understanding, education, and clinical training in pharmacovigilance; and effective communication to the generic public. [10]

Fig : key goal of Pharmacovigilance

- To improve patient care and safety when use of medicines all medical and para medical inventions.
- Identify the efficacy of drug and by monitoring the advers effect of drug from lab to the pharmacy and then for years.
- Improve public health, safety and efficacy.
- Contribute to the assessment of benefits ,harm, effectiveness and risk of drugs ,encouraging their safe ,rational and more effective use.
- Promote understanding, clinical training and education in pharmacovigilance and it's communication to the people.
- Pharmacovigilance keeps of any drastic effect of drug.

National Programme of Pharmacovigilance (6):

Before a product is marketed, experience of its safety and efficacy is limited to its use in Clinical trials, which are not reflective of practice conditions as they are limited by the patient Numbers and duration of trial as well as by the highly controlled conditions in which Clinical Trials are conducted. The conditions under which patients are advised during the pre-Marketing phase do not necessarily reverse the way the medicine will be used in the hospital or any other . once it is marketed. Information about rare but serious adverse drug reactions, chronic toxicity, use in special Groups (e.g. pregnant women, children, elderly) and drug interactions is often incomplete or Not available. Certain adverse drug reactions may not be checked up to a very large number of People have received the medicine. Pharmacovigilance is therefore one of the important post-marketing tools in ensuring the Safety of pharmaceutical and related health products.

- Assessing the risks and benefits of medicines in order to determine what action, if any, is Necessary to improve their safe use.
- Providing information to pateint to enhance safe and effective use of medicines.
- Monitoring the impact of any action taken

The Pharmacovigilance Programme of India (PvPi) (5):

The need for a strong Pharmacovigilance system for safeguarding public health was soon realised by the regulatory authority, NPP was renamed the Pv programme of India (PvPi).which started functioning from 14 July 2010,with the all India institute of medical science (AIIMS) as the national coordination Centre (NCC).in order to monitor the ADRs in all over the India ,this programme has 22 ADR monitoring centre, including AIIMS and new delhi. the NCC was later shifted from AIIMS to Indian pharmacopiea commission (IPC) Gaziabad on 15 April 2011 , for effective implementation. the aim of generating independent data on the safety of drug to match the global safety monitoring standard. because of Pv was considered to be a programme that monitor proscriptions for ADE and medication errors ,some clinicians was being doubted . the PvPl attempt hard work to overcome

this challenge for understanding and to eliminate the reason for understanding by way of conducting several continued medical education, awareness and training program for HCPs on Regular loss to educate them and habit of reporting of ADRs introduce.

Goals of PVPI: (6)

Short term goals:

- To develop and implement pharmacovigilance system in India
- To encourage the health professionals in reporting of adverse drugs, vaccines, medical devices, and biological Products
- Collection of case reports and data.
- All MCI approved medical colleges conducted the programs.

Long term goals:

- To expand the pharmacovigilance programme to all hospitals and centers public health programs located in India
- To make ADR reporting mandatory for healthcare professionals.
- To develop and electronic reporting system.

The National pharmacovigilance centre : (6)

At present,post-marketing surveillance of Drugs is substantiallyco-ordinated by public Pharmacovigilance centres. In collaboration With the Uppsala Monitoring Centre(UMC) The National Centres have achieved a great Deal in

- Collecting and analyzing case reports of ADRs
- Distinguishing signals from background ‘ noise ’
- Making nonsupervisory opinions grounded on Strengthened signals
- Waking prescribers, manufacturers and the Public to new pitfalls of adverse responses.
- The number of National Centres Sharing in the WHO International Drug Monitoring Programme has increased from 10 In 1968 when the Programme started to 67 in 2002. The centres vary vastly in size, Coffers, support structure, and compass of Conditioning. Collecting robotic reports of Suspected ADRs remains their core exertion .

National Pharmacovigilance centre responsible for : (1)

- Promoting the reporting of adverse Reactions;
- Collecting case reports of adverse Reactions;
- Clinically evaluating case reports;
- Collating, analyzing and evaluating Patterns of adverse reactions;
- Distinguishing signals of adverse reactions From “noise”;
- Recommending or taking regulatory action In response to findings supported by good Evidence;
- Initiating studies to investigate significant Suspect reactions

National centres have played a significant role In increasing public awareness of issues Relevant to the safety of medicines. As a result, In some countries, pharmacovigilance is Increasingly being seen as much more than a Regulatory activity as it also has a major part to Play in clinical practice and the development Of public health policy. This development is Partly attributable to the fact that many National and regional centres are housed Within hospitals, medical schools or poison And medicine information centres and is in Collaboration with a Medicines Regulatory Authority (MRA). The scope of activities of National centres has expanded to include Communication of information about the Benefits, harm and effectiveness of medicines To practitioners, patients and the public. The Central Drugs Standard Control Organization (CDSCO) is initiating a country-Wide pharmacovigilance programme under The aegis of DGHS, Ministry of Health & Family Welfare, and Government of India. The programme shall be

interdependent by the National Pharmacovigilance Centre at CDSCO. The National Centre will operate under the supervision of the National Pharmacovigilance Advisory Committee to Recommend procedures and guidelines for Regulatory interventions.

What to report?

The National Pharmacovigilance Programme (NPP) shall encourage reporting of all Suspected medicine affiliated adverse events, Including those suspected to have been caused By herbal, traditional or indispensable remedies. The reporting of putatively insignificant or Common adverse responses would be Important since it may punctuate a wide Defining problem.

- All adverse events suspected to have been Caused by new drugs and 'Drugs of current Interest' (List to be published by CDSCO from Time to time.
- All suspected drug interactions
- responses to any other medicines which are Suspected of significantly affecting a case's Operation,
- including responses suspected of causing Death
- Life- hanging (real threat of dying)
- Hospitalisation (original or prolonged)
- Disability (significant, patient orEndless)
- natural anomaly
- needed intervention to help Endless impairment or damage

Who can report - Any health care professionals (Doctors Including Dentists, Nurses, and Pharmacists) May report suspected adverse drug events. The Programme shall not accept reports from Lay members or anyone who Is not a health care professional.

Where to report - After completion the form shall be Returned/ encouraged to the same Pharmacovigilance Centre from where it was Entered. Reporting can be done to any one of The country vide pharmacovigilance Centres Nearest to the journalist. In case of misdoubt the form May be transferred to the public pharmacovigilanc Centre at Central medicines Standard Control Organisation, New Delhi.

What happens to the information submitted?

The records withinside the shape will be handled in strict confidence. Peripheral Pharmacovigilance Centres shall ahead the shape to the respective Regional Pharmacovigilance Centres who will deliver out the causality analysis. This records shall be forwarded to the Zonal Pharmacovigilance Centres. The statistics could be statistically analysed

and forwarded to the global Pharmacovigilance Database controlled through WHO Uppsala Monitoring Centre in Sweden. The very last file primarily based totally at the analysed statistics could be periodically reviewed through the National Pharmacovigilance Advisory Committee constituted through the Ministry of Health and Family Welfare. The Committee is entrusted with the obligation to study statistics and propose any regulatory interventions that can be required with admire to the drug or magnificence of drug.

Future perspective:

For the problem and challenges facing the development of a Strong Pv system of India, the following properties might be as follows.

- Build and maintain a Strong Pv system.
- Making Pv reporting mandatory and introducing Pv inspections.
- High level discussion with various stakeholders.
- Education and training of medical student, pharmacist, nurses in the area of Pv.
- Collaborating with Pv organization in enhancing drug safety with advancement in information technology, their has been emergence of new opportunities for national and international collaboration that can post marketing surveillance program and increase drug safety.

3. CONCLUSION

In India Pv is a continue to grow, evolve and improve. Pv looks at all available information to assess the safety profile of a drug . Pharmacovigilance required for identifying and correlating drug and their side effects and taking corrective actions. The PvPi has strived energetic to achieve its goal. When adverse effects and toxicity do appear when presioly unknown it is essential that they are reported, analysed and their importance communicated effectively to an audience that has knowledge to explain the information which carry an unavoidable and some for all medicines there is a trade of between the benefits and the potential to harm. the harm can be minimised by ensuring that medicines of good quality, safety and efficacy are used rationally and that the expectations and concern of the patient are taken in to account when therapeutic decision are made to achieve this is to.

- Save public health
- Ensure that risks in drug used are anticipated and managed
- Provide regulators with the necessary information to amend the recommendation on the use of the medicine.
- Educate health professionals to understand the effectiveness/risk of medicine that they prescrib. This is the important role of Pharmacovigilance.

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