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PHARMACOVIGILANCE: A KEY FOR DRUG SAFETY AND MONITORING

Pankaj Bhogam, Vivek Durgule, Sushant Gharal

Anandi Pharmacy College, Kalambe Tarf Kale, Dist. Kolhapur, India.

ABSTRACT

Pharmacovigilance idea given by the global Health Organization (World Health Organization) because the science and series of activities about the detection, evaluation, understanding rejection of adverse impact and a clinical test could be an analysis study in human volunteers to answer specific health queries. The aim of pharmacovigilance is to improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions. They detect problems related to the use of medicines and communicate the finding in a timely. The Pharmacovigilance has been recognizing to play a crucial role in the rational use of the drug by providing data concerning the adverse impact. The information of Adverse Drug Reaction (ADRs) is often increased by numerous suggests that such information studies, intensive observation, spontaneous reportage and different new method at dictatorial and scientific level square measure being developed with the intention of step-up Pharmacovigilance. As a result of assessment strategies are not entirely void of individual judgments, integrator dependence is often low. In conclusions, there's still no methodology universally accepted for casualty assessment of ADRs.

Keywords*:* - Adverse Drug Reaction, Clinical test, Pharmacovigilance, Treatment

INTRODUCTION

According to the World Health Organization, "Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effect or any other possible drug-related problem, particular, long term and short-term adverse effects of medicines". The history of the word "Pharmacovigilance" are Pharmakon (Greek word of 'drug') and vigilare (Latin word for 'to keep watch').

Pharmacovigilance is not new to Asian nation and has infect been going on from 1998. When Asian nations decided to join the Uppsala centre for adverse event monitoring. Observation of adverse drug reaction and adverse events is an important tool for gathering the safety data for early detection. It is widely accepted that a drug has to go through various phases of trial to establish its safety and efficacy before it is marketed commercially. Limitations of clinical trials, like; strict criteria of inclusion and exclusion make it to be used in a very selective group of patients; special population groups like kids, pregnant lady, and maturity population are not studied during the trials; and other factor causing drug reactions such as genetic factors, environmental factors, and drug-drug interactions may not have been studied during the clinical trials.

METHOD OF CAUSALITY ASSESSMENT

Many researchers developed in pharmacovigilance, numerous ways of relation assessment of ADRs by mistreatment totally different criteria like chronological relationship between the administration of the drug and occurrence of the ADR, screening for non-drug connected causes, confirmation of the reaction by in vivo or vitro tests, and former data on similar events attributed to the suspect drug or to its therapeutic category, etc. to outline ADRs in several categories. However, as a result of there aren't any outlined diagnostic criteria or classes, inter-rater and intra-rater variability may be large**.** Currently, there's no universally accepted ways of accessing relation of ADR.

Table 1: HISTORY OF PHARMACOVIGILANCE IN ASIAN NATION

Year	Development
1747	Very first known clinical trials by James Lind, proving the usefulness of lemon juice in preventing scurvy
1937	Death of more than 100 children due to toxicity of sulfanilamide.
1950	Aplastic anemia reported due to Chloramphenicol toxicity
1961	Worldwide tragedy due to thalidomide toxicity
1963	16th World Health congregation recognize significant to rapid action on Adverse Drug Reactions (ADRs)
1968	WHO research project for international drug monitoring on pilot scale
1996	Global standards level clinical trials initiated in India

1997	India attached with WHO Adverse Drug Reaction Monitoring Program
1998	Initiation of Pharmacovigilance in India
2002	67th National Pharmacovigilance Center established in India
2004-05	India launched National Pharmacovigilance Program
2005	Accomplishment of structured clinical trials in India
2009-10	Pharmacovigilance Program (Pv. PI) started

Pharmacovigilance in Asian nation started from 1986. A proper Adverse Drug Reaction (ADR) watching system was initiated with twelve regional centers, every covering a population of fifty million. However, no noteworthy growth was created. Later in 1997, Bharat joined the world Health Organization (WHO) and Adverse Drug Reaction (ADR) scrutinized program primarily based at 2 urban centers, Kingdom of Sweden however got fail.

AIM OF PHARMACOVIGILANCE

Improvement of patient care and safety in respect to use of medicines with medical and paramedical interventions remains to be a crucial parameter. The main objectives of Pharmacovigilance involve exhibiting the effectuality of medicine by observation their adverse impact profile for several years from the research lab to the pharmacy; trailing any forceful impact of drug rising public health and safety respect to the utilization of medicines; encouraging the safe, rational and efficient use of drugs; promoting understanding, educations and clinical coaching in Pharmacovigilance; and effective communications to the generic public.

METHODS UTILIZED IN PHARMACO-VIGILANCE

The activities undertaken in the name of Pharmacovigilance can be roughly divided into three groups: regulatory, industry, and academia. Regulatory Pharmacovigilance is driven by the aim to provide drugs with a positive benefit- harm profile to the public. Some of the problems related to regulatory post-marketing surveillance will be discussed in this context, followed by a description of the methods used to detect new ADRs and a discussion of the pros and cons of each method.

1. Dangaumou's French method
2. Kramer et al. method
3. Naranjo et al. methodology (Naranjo scale)
4. Balanced assessment method
5. Ciba-Geigy method
6. Loupi et al. method

7. Roussel Uclaf Casuality assessment method
8. Australian method

ADVERSE DRUG REACTION (ADRs)

An adverse drug (ADRs) is outline as AN fortuitous and harmful to a health product that causes at the doses sometimes or tested for the diagnosing, hindrance or treatment of a malady or the alteration of AN organic function Though, it's tough to acknowledge the actuating agent connected with the adverse drug reaction (ADRs) encountered contain quite ingredients. The magnitude of risk must be thought-about together with magnitude of expected medical specialty advantages decide whether or to use a specific drug in an exceedingly given patient. Adverse drug Reaction (ADRs) are classified in two ways-

1. Foreseeable (Type-A) Reaction
2. Unpredictable (Type-B) Reaction

Predictable (Type-A) Reaction: This square measure supported pharmacologic properties of the medicine like increased however quantitatively response to the drug that embody aspect effects, Gyanogenic effects and consequences of drug withdrawal.

Unpredictable (Type-B) Reaction: This square measure supported peculiarities of patient and not on drug's acknowledged actions; embody allergic reaction and specialty. These are less common, usually non dose connected, typically a lot of serious and need withdrawal of drug. An inventory of some suspected and acknowledged medicine related to adverse effect.

Table 2: The known Drug and its adverse effect

Drug	Adverse Drug Reactions (ADRs)
Thialidomide	Phocomelia, Multiple defects
Methotraxate	Multiple defects, Foetal death
Androgen	Virilization, limb, esophageal, cardiac defects
Progestins	Virilization of female foetus
Stilboestrol	Vaginal carcinoma in teenage female offspring
Tetracyclines	Discolored or deformed teeth, retarded bone growth
Warfarin	nose, eye and hand defects, growth retardation
Phenytoin	Various malformations
Lithium	Foetal goiter, cardiac and other abnormalities
Aspirin/Indomethacin	Premature closer of ductus arteriosus

CLINICAL TRIAL

A clinical trial could be an analysis study that tests a replacement medical treatment or a replacement manner of mistreatment Associate in Nursing existing treatment to ascertain if it'll be good to stop and screen for diagnose or treat disease. Wide selection of dose of the study drug is given to Associate in Nursingimals subjects or to an in-vitro [outside the body] substrate so as to get preliminary effect, toxicity and pharmacokinetic information.

Before pharmaceutical company begin clinical trials on a drug, they conduct in depth pre-clinical studies.

Pre-Clinical Studies

Pre-clinical studies involve in vitro (i.e. outside the body) studies and trial or animal population. Wide travel dose of the study in drug area unit given so as to get preliminary effect, toxicity and pharmacokinetic data and to help pharmaceutical company decide whether or not it's worthy to travel ahead with more testing.

Clinical Studies

Phase-0

Phase zero may be a recent designation for exploratory, first-in-human trial conducted in accordance with U.S. food and Drug administration (FDA) 2006 steerage on exploratory. Phase 0 studies use only few small doses of a new drug in a few people. They might test whether the drug reaches the tumor, how the drug acts in the human body and how cancer cell responds to the drug. The administration of single sub-therapeutics doses of the study drug to a little range of subjects (10-15) to collect preliminary information on the agent's pharmacological medicine (how to body processes the drug) and Pharmacodynamics (how the drug adds the body).

Phase-I

Phase I is 1st stage of testing in human subject. Generally, test a new drug candidate in healthy volunteers. In most cases 20to80 healthy volunteers participate in phase 1. The primary purpose of phase 1study to evaluate the safety of a new drug candidate before it proceeds. This part includes trails designed to assess the security (Pharmacovigilance) tolerability, pharmacological medicine and Pharmacodynamics of a drug.

There are unit totally different styles of clinical trial trials.

SAD: Single ascending dose studies are usually conducted in a small number of healthy volunteers. This is use to find out the safe dose range.

MAD: Multiple ascending dose studies are intended to fully characterize the pharmacokinetic of a drug and its metabolites at steady state, investigate a drug's accumulation potential, explore its dose proportionality and determine the maximum tolerated dose.

Phase-II

A phase 2 clinical trial tells more about how safe the treatment is and how well it works. clinical trial studies area unit generally divided into clinical trial A and clinical trial B. clinical trial A is specifically style to access dosing necessities (what proportion drug ought to be given), wherever as clinical trial B is specifically designed to check effectualness (however well the drug works the prescribed dose).

Phase-III

Phase III studies irregular controlled multi-center trials on giant patient's cluster (300-3,000 or additional relying upon the disease/ medical condition studied). A study that tests the safety and how well a new treatment works compare with a standard treatment. For example, phase 3clinical trails may compare with group of patient has better survivals rates fewer side effects

Phase-IV

Phase IV trial is additionally called Post promoting police work Trial. Phase IV trials involves the security police work (Pharmacovigilance) phase IV clinical trials is the type of clinical trials that studies the side effect caused over time by a new treatment after it has been approved and is on the market.

CONCLUSION

The Pharmacovigilance has been recognizing to play a crucial role in the rational use of the drug by providing data concerning the adverse impact. The information of Adverse Drug Reaction (ADRs) is often increased by numerous suggests that such information studies, intensive observation, spontaneous reportage and different new method at dictatorial and scientific level square measure being developed with the intention of step-up Pharmacovigilance. In conclusions, there's still no methodology universally accepted for casualty assessment of ADRs.

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