JETIR.ORG ISSN: 2349-5162 | ESTD Year : 2014 | Monthly Issue
JOURNAL OF EMERGING TECHNOLOGIES AND INNOVATIVE RESEARCH (JETIR)
An International Scholarly Open Access, Peer-reviewed, Refereed Journal

A REVIEW ON: PHARMACOVIGILANCE AND IT'S IMPORTANCE

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Abstract

Pharmacovigilance supports safe and appropriate use of drugs. Spontaneous reporting of adverse drug reactions (ADRs) is an essential component of pharmacovigilance. However, there is significant underreporting of ADRs. Adverse drug reactions have become a major problem in developing countries. Knowledge of pharmacovigilance could form the basis for interventions aimed at improving reporting rates and decreasing ADRs. Pharmacovigilance supports safe and appropriate use of drugs. Spontaneous reporting of adverse drug reactions (ADRs) is an essential component of pharmacovigilance. However, there is significant underreporting of ADRs. Adverse drug reactions have become a major problem in developing countries. Knowledge of pharmacovigilance could form the basis for interventions aimed at improving reporting rates and decreasing ADRs.

Pharmacovigilance promotes the appropriate and safe use of medications. Adverse drug responses (ADRs) must be reported spontaneously, and this is a crucial part of pharmacovigilance. ADRs are, nonetheless, considerably underreported. In developing nations, adverse medication responses are now a significant issue. Understanding pharmacovigilance could serve as the foundation for actions meant to increase reporting rates and lower ADRs. Pharmacovigilance promotes the appropriate and safe use of medications. Adverse drug responses (ADRs) must be reported spontaneously, and this is a crucial part of pharmacovigilance. ADRs are, nonetheless, considerably underreported. In developing nations, adverse medication responses are now a significant issue. Understanding pharmacovigilance could serve as the foundation for actions meant to increase reporting rates and lower ADRs.

Keywords: Pharmacovigilance, drug security, clinical studies, adverse drug reaction.

Introduction

The manner that diseases are treated has altered as a result of drugs. Adverse responses are a known risk of medicat ion therapy, despite all the benefits of pharmacotherapy. A prevalent and frequently avoidable cause of disease, disa bility, and death is an adverse drug response (ADR). According to one definition, an ADR is "an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts risk from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product."[1] According to the world health organization, "Pharmacovigilance is defined as the science and actions connected to the detection, assessment, understanding, and prevention of adverse effects or any other potential drug-associated problem, especially long- and short-term harmful effects of medicines."[2] A crucial and integral component of clinical research is pharmacovigilance. Throughout the whole life cycle of a product, post-

marketing pharmacovigilance (often referred to as Post marketing studies or Phase IV clinical trials) and clinical trials safety are both essential. The pharmaceutical business as well as other regulatory authorities worldwide have upped the bar in response to the unusually high number of recent high-profile drug withdrawals. Major pharmaceutical corporations have now adapted early detection of signals from post-marketing surveillance studies and clinical trials in early phases in order to identify the hazards connected with their medicinal product(s) as early as feasible. If such a risk exists, it is necessary to implement appropriate risk management strategies throughout the product's life cycle. These risk management strategies are also frequently referred to as risk minimization programmes.[3]

History of pharmacovigilance

In India, pharmacovigilance began in 1986. There was no notable expansion made despite the formal Adverse Drug Reactions (ADR) monitoring system being launched with 12 regional centres each serving a population of 50 milli on. India thereafter joined the Adverse Drug Reaction (ADR) monitoring programme run by the World Health Orga nization (WHO) in 1997[4]Uppsala, Sweden, but failed. As a result, the National Pharmacovigilance Programme (NPPV) of India, which is supported by the WHO and is funded by the World Bank, became operational after 2005.[4][5][6]

Importance of pharmacovigilance

Pharmacovigilance is a crucial and essential component of clinical research. Throughout the product lifecycle, post marketing pharmacovigilance as well as clinical trial safety are essential. In India, pharmacovigilance is still in its

infancy and there is very little information available on the subject. While the western countries have made signific ant strides in the field of pharmacovigilance, India has not made as much progress. It is crucial to comprehend the significance of pharmacovigilance and how it affects the product's life cycle. This will make it possible to incorpora te best practises for pharmacovigilance into the procedures and processes used to assure regulatory compliance, imp rove clinical trial safety, and monitor products once they are put on the market. Since India's decision to join the Up pasla centre for adverse event monitoring in 1998, pharmacovigilance has been practised in that country. Withdrawals, regulatory bodies, the media, and increased consumer awareness of the advantages and risks of medications all highlight the significance of pharmacovigilance[7]

The importance of pharmacovigilance is as follows:

- Pharmacoepidemiological trials
- safety monitoring of pharmaceuticals
- Case reports
- case series development
- case series analysis
- data mining to find product-event combinations
- spontaneous reporting[8]

Aim of pharmacovigilance

The aims of pharmacovigilance are:

- Enhance patient care and safety with regard to medication use and all other medical and non-medical treatments.
- Study the effectiveness of medications and keep track of any negative side effects by following them from the lab to the pharmacy and beyond for a long time.
- Pharmacovigilance monitors any severe side effects of medications.
- Boost public safety and health with regards to the use of medications.
- Encourage the safe, intelligent, and more effective (including cost-efficient) use of medicines by helping to analyse their benefits, harms, effectiveness, and risks.

- Promote public awareness, knowledge, clinical training, and effective communication of pharmacovigilance [9]
- Finding instances of improper medication administration.
- A product's pharmacological/toxicological features are clarified more, and the way that it causes negative drug reactions.
- The identification of important drug-drug interactions in co-therapy and novel products.
- a market with agents already established, which might only be discovered during extensive application.
- The comparative profile of negative medication reactions among drugs belonging to the same therapeutic class[10]

Adverse drug reactions (ADRs):

An adverse drug reaction (ADR) is characterised as an undesirable and harmful reaction to a health product that occurs at dosages typically used or tested for the diagnosis, prevention, or treatment of a disease or the altering of th e an organic function[11][12][13]

Adverse drug reactions (ADRs) have been classified in to two ways;[14]

A.Predictable (TypeA) Reactions

These are based on the pharmacological characteristics of the drug, such as an increased but quantitatively typical r eaction to the drug, which includes adverse effects, toxic effects, and withdrawal symptoms.[15][16]

B. Unpredictable (Type-B) Reactions

These are based on patient quirks rather than the known effects of the medicine; examples include allergy and eccentricity. They are less frequent, frequently not dose related, typically more dangerous, and call for drug discontinuation.[15][16]

Table 1. Known drugs adverse effects[17]

Drug	Adverse Drug Reactions (ADRs)
Thalidomide	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

Monitoring of ADRs

The process of continuously monitoring adverse drug reactions (ADRs) is known a ADRs monitoring. Pharmacovig ilance is crucial to the role of ADR monitoring[18]

If any of the adverse events are not disclosed, the therapeutic products amay have unpleasant and detrimental effect s. Thus, carrying out ADR monitoring programmes correctly will contribute to minimising the negative effects of m edicinal drugs..

Benefits of ADR monitoring

- It provides details on the reliability and security of medicinal items.
- Plans for risk management are started.
- It aids in measuring ADR adherence and prevents the predictable adverse effects.
- It raises awareness of ADRs and educates the health care team, including patients, pharmacists, and nurses, about adverse drug reactions.

ADR monitoring's primary goals are to detect the risk variables that can result in adverse reactions, as well as to disclose the kind, quantity, and frequency of ADRs[18]

Conclusion

The only way to guarantee that a medicine is safe over its entire life cycle is through pharmacovigilance. is extremely important since clinical studies often struggle to find unusual and extremely rare ADRs. There is a wealth of information and knowledge accessible regarding the safety of any drug. Drug regulators must make the right decisions to protect the public's health. The majority of ADRs are reported by healthcare practitioners. However, there are substantial amounts of Worldwide underreporting reported. It is today's biggest challenge. Nevertheless those Despite

its drawbacks, the spontaneous reporting system continues to be the most popular way to report ADRs and can produce signals for rare and extremely rare types of ADRs. If every medical care Professionals.

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