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Pharmacovigilance for Drug Safety Monitoring

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Research Article

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ABSTRACT

Now a day's usage of medicine has been increasing day by day and pharmaceutical companies are developing new drug products and humans begin taking more and effective drugs as well as investigational drugs. Safety and efficacy are the two major predominant considerations about any drug. In each and every phase of a products life cycle pharmacovigilance plays a critical role. Thus, significance of pharmacovigilance is developing and became very important and inseparable part of clinical research.

Keywords: Pharmacovigilance, Adverse Drug Reaction, Post Marketing Surveillance.

INTRODUCTION

Pharmacovigilance is majorly known as drug safety. It is a main integral part of clinical research. Throughout the product life cycle clinical trials safety and post marketing pharmacovigilance plays a critical role [1-3]. The word pharmacovigilance is derived from two words one *Parmakon* is a Greek word which means "drug" and another *vigilare* is a Latin word which means to keep awake or to keep watch." Pharmacovigilance is "defined as the pharmacological science relating to the detection, understanding, assessment and prevention of adverse effects, particularly long term and short term adverse effects of medicines" [4-8].

According to WHO Pharmacovigilance (PV) is the pharmacological science relating to the detection, evaluation, understanding and prevention of adverse effects, especially long term and short term side effects of medicines [9].

AIMS OF PHARMACOVIGILANCE

- ✓ To improve patient care & safety
- ✓ To contribute to assessment of benefit, harm & effectiveness of medicine
- ✓ To Identify previously unrecognized adverse effects of the drugs
- ✓ To Promote rational & safe use of medicine
- ✓ To Promote education & clinical training
- ✓ To Identify patient related risk factors of ADR such as dose, age, gender
- ✓ Any response to a drug which is unintended , occurs at particular doses
- ✓ To diagnose or therapy of disease, or for the modification, of physiological function.

Pharmacovigillance helps in removal of approved and licensed products from the market because of clinical toxicity, which is caused by adverse drug reactions in the body. Below is a short note on adverse drug reactions [10-19].

Adverse Drug Reactions

ADR is a response to drug, which alters the normal physiological function of the body, factors which causes ADR includes mainly multiple drug therapy, age & gender.

They are mainly two types of ADR

TYPE A: These are common, predictable, dose dependent, they are seldom fatal

TYPE B: These are uncommon, unpredictable, dose independent; they involve relatively high rates of serious morbidity [20-26].

High index of ADRs are to be successfully diagnosed by clinicians, it is the high level of awareness about the drugs being used. Pharmacovigilance, unify all the information in all aspects of benefit-risk ratio of drugs in a population [27-34]. Events that occur when a particular drug is administered are recorded in the patient's notes by drug monitoring then an adverse reaction of the drug and the activity of the drug being monitored; these studies aim to detect ADR of drugs [34-39].

Reporting of ADRs after marketing must be actively encouraged and should involve all those concerned including doctors, pharmacists, nurses, patients and pharmaceutical companies. To develop and enhance this, a culture of learning about pharmacovigilance for health care students must be started in their early professional carrier [40-45]. This will help healthcare professionals to understand and also create awareness by giving adequate information to patients at their initial phase of treatment about the potential benefits and risks of the therapy [45-52].

In the process of development of a new pharmaceutical drug, there are many stages they are preclinical trails, then clinical trials this includes four phases. In this the first three phase's helps in the determination of safety, efficacy and side effects of the developed drug product respectively, whereas in case of fourth phase post marketing studies are carried out for determining safety in patients. Thus post marketing surveillance helps in uplifting the knowledge of pharmacovigilance [53-59].

POST MARKETING SURVEILLANCE

Pharmaceutical drug or medical device is monitored often after it has been released in to the market, Since drugs are approved based of clinical trials which involve relatively small number of people who do not have any other medical complications, post marketing surveillance play an important role to know the ADRs of drugs after they have released in to the market [60-67].

Approaches by

- ✓ spontaneous ADR reporting
- ✓ Prescription event monitoring
- ✓ Electronic health records
- ✓ Patient Registers

Spontaneous ADR Reporting

It is necessary to report ADRs to Pharmacovigilance department by doctors, health care professionals, they are provided with forms where they can notify the suspected ADRs they detect, these forms are greatly available to health care professionals to encourage the reporting, it helps in spontaneous reporting for all the drugs, it is affordable method of detecting rare ADRs. This spontaneous reporting helps to identify many unexpected ADRs, it helps in withdrawal of many marketed drugs, and information being provided which guide safer use of the product [68-76].

ADRs which occurred by particular drugs should be analyzed and reported, Pharmaceutical manufacturers have to communicate with the doctors at the clinical level regarding the ADRs by [77-82].

- ✓ Changing Medication formula if necessary
- ✓ Implementing new prescribing procedures
- ✓ Implementing new dispensing procedures
- ✓ Educating the professional staff
- ✓ Educating Patients

Prescription Event Monitoring

It involves health professionals submitting all the clinical events reported by the patient to the prescribed new drug [83].

This method mainly focusses on studying the safety of new medications that are used by general practitioners in this method [84].

In this method patients being prescribed by drugs are monitored [85].

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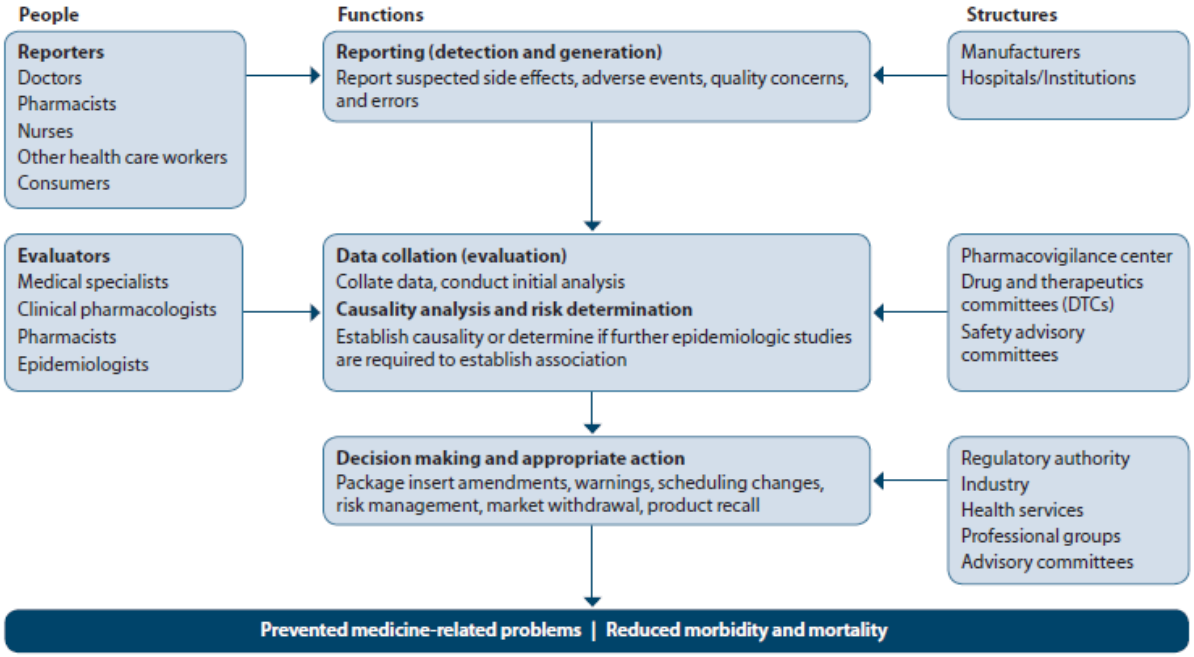

Figure 1: The Pharmacovigilance Frame work

Electronic Health Records

It is a computer stored collection of health information, about one person linked by a person identifier; it represents the basis for healthcare Information system development [86].

Patient Registers

To bring together patient records, it is time consuming and less expensive [87].

PHARMACOVIGILANCE PROGRAMME OF INDIA (PVPI)

It officially starts on 23rd November 2004 at New Delhi, is under the control of CDSCO (Central Drug Standard Control Organization), Directorate general of health services, Indian pharmacopeia commission (Ghaziabad) [88-94]. The program is conducting by NCC (National Coordinating Centre) to ensure that the benefits of use of medicine against the risks [95-103].

Objectives:

- ✓ To monitor ADRs
- ✓ To create awareness among health care professionals about ADRs
- ✓ To monitor benefit-risk profile of medicines
- ✓ Support the CDSCO

CONCLUSION

Pharmacovigilance gives information to assess the safety profile of a drug; the success of pharmacovigilance is largely dependent on the participation of professionals of health care countrywide to report ADRs/AEs, Current progress in Pharmacovigilance is marked by increase in use of databases to make the process more proactive and organized. It must be in everyone's interest to develop safe and effective medicines to patients.

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