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Mini Review

Pharmacovigilance in India and Its Challenges

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ABSTRACT

The thalidomide disaster is a turning phase in the expansion of Pharmacovigilance (PV) worldwide. Pharmacovigilance is very critical to the healthcare system for the safe treatment of an individual. Drugs are designed to cure, prevent or for treatment, alongside drugs can also cause harm to the patient in terms of ADR (Adverse Drug Reaction). PV should be an integral part of the healthcare system, especially in countries like India, where there are over one billion drug consumers, however until now pharmacovigilance is a new concept in many developing countries. This article provides a complete overview of pharmacovigilance and pharmacovigilance programs that are doing outstanding jobs in India to eradicate the ADR of drugs. It will also highlight the journey of pharmacovigilance in India.

Keywords: PV; PVPI; ADR; Clinical trials; WHO

INTRODUCTION

The exemplary saying "Drugs are kind of poison" is dated several years ago, as almost all medicine have adverse drug reactions that comes along with the therapeutic effect [1]. ADR are the effect of drugs that are unintended and occurs at a normal dose of the drug [2]. Adverse drug reactions not only affect the health of an individual but also result in economic loss for society [3]. Pharmacovigilance was introduced after the publication of McBride who suspected phocomelia (a kind of fetal deformities) due to the use of a drug named thalidomide (used as an anti-emetic and sedative agent) in pregnant women. Pharmacovigilance is primarily defined as assessing the chances of side effects during the therapy [4,5]. According to WHO pharmacovigilance is defined as the science of detection, assessment, understanding and prevention of drug-related problems [6]. Pharmacovigilance systems are internationally designed to track the ratio of risk and benefit of the drug to maintain the safety and to uplift the quality of life [7]. WHO begins the pharmacovigilance project with the collaboration of ten countries? These partner countries laid out the required information for the databank, with time more countries across the world joined the WHO Programme for International Drug Monitoring (PIDM). 150 countries till now joined the programme. The PV focuses on the detection of ADR, calculation of risk-benefit ratio and circulation of information to the healthcare professionals, pharmaceutical companies and the public [8,9]. PV should be empowered in every country to establish a rock strong healthcare system and to provide a rational and individualized treatment to a patient.

CLINICAL TRIAL AND ITS LIMITATION

Pharmaceutical companies spend billions to release a new drug into the market. A drug before being introduced in the market goes through phases of trials to determine its safety, but the safety findings have restrictions and deformity [10]. Effects are noticed in animal studies before introducing the drug to human, then the drug enters into phase-I and phase-II studies and finally in phase-III trial. Even the highest care and caution at the clinical trial can't ensure the absolute safety of the drug as these trials are run over a limited period of time, under a restrained environment, on the finite number of meticulously selected individuals based on established criteria [11,12]. Post marketing pharmacovigilance or phase-IV trial uses gear such as data mining and examination of case reports which narrate the original drug safety profile (Figure 1) [13].

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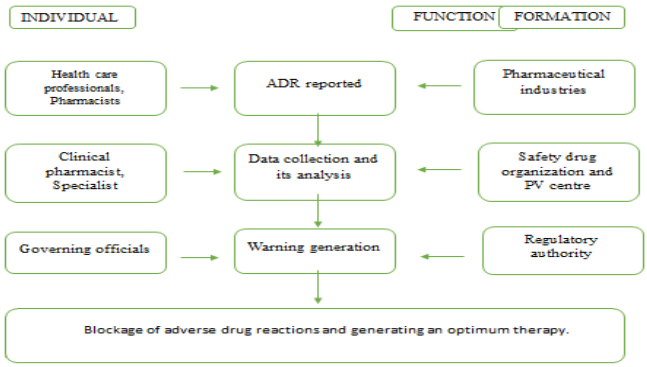

Figure 1: Working of Pharmacovigilance.

SCOPE OF BARRIERS OF PHARMACOVIGILANCE

Pharmacovigilance from its establishment till now is a well active and scientific authority. It has been very crucial to face the challenges of the growing range of medicines including vaccines, which sustain the inescapable and uncalculated effects of harm. The possibility of harm can be minimized by practicing PV at clinical, production and the administration levels. This scope of PV has somehow been attained but several challenges restrict the blossoming and development of pharmacovigilance activities [14]. These challenges are listed below:

- Reporting of ADR- Reporting is the base for detection of ADR, especially in case of new and undiscovered adverse drug events. Despite all excellence of reporting low reporting is one of the barriers to the development of PV [15]. Data mining should be practiced after keeping the fact of low reporting system of different medicine, also signals thus be assessed while acknowledging the chances of faulty positives [16]. Low-income countries have a low rate of reporting when compared to developed countries [17].
- Awareness- Lack of awareness about PV program among the population, pharmacist and other health care professional is the factor that play role in obstructing PV program in developing countries. It is also the main problem in reporting ADR which is the main step for detection of ADR [18,19].
- Financing budget- Low economic countries mostly have a very finite budget for the healthcare system and financing in PV is not the priority of these countries. Low funding is a heartfelt obstruction that developing countries face [20].
- Reporting form- Information about any ADR can be shared in various ways; ADR form is one of the main ways for sharing the information. The ADR form should be well-designed, easy to understand, correct and must contain necessary points about patient information and the suspected ADR [21].

Importance of PV in developing countries

In the last few years, the awareness among low economic countries is rising on upgrading the safety of the patient while using a particular drug. WHO focuses on developing a mechanism of drug safety in almost every country worldwide? Developing countries depend on developed countries for information about drug safety, but it is a necessity of establishing native ADR management programs because of differences in dosage, excipients used, digitalization, and awareness and due to other factors like self-medication habits, physician-focused hospital systems, errors in medication (manufacturing, dispensing, administration etc.), differences in the genetic build-up, the difference in the environment. Data obtained from the developed world is separate in terms of geomorphology, prescription pattern and utilization of drugs. Hence an indigenous PV program with a local database is a necessity every country especially the countries with a large population [22].

PV IN INDIA

Monitoring of adverse drug events in India expand relatively late, as conventionally the notion of surveillance is not there. The first ADR surveillance centres with 12 regional centres were established in 1986 after the work of a few physicians on ADE and sensible prescribing. These Centres was unsuccessful as each covers millions of population. A new start was seen when India joined the WHO programme in Uppsala, Sweden. 3 centres were established with the main aim to report ADR to the authority of India but howsoever this also failed due to lack of funding [23].

PV was again relaunched by the Indian government, named the National Programme of Pharmacovigilance (NPP) with the help of the World Bank in 2004-2005. The NPP monitor the PV programme nationwide under the Ministry of Health and Family Welfare. NPP focuses on reporting and collecting information at the zonal level, then putting these reports forward to Central Drugs Standard Control Organization (CDSCO) as well as to UMC (Uppsala Monitoring Centre). Unluckily the programme was suspended in 2009 due to lack of funding from the World Bank [24].

Current PV programme in India

The frame of the new or current program was formulated in a joint workshop of AIIMS New Delhi and CDSCO and named as Pharmacovigilance Programme of India (PVPI) in 2010. 22 ADR monitoring centres including AIIMS New Delhi are set up countrywide [25]. AIIMS New Delhi was established as a National Co-ordination centre which in 2011 shifted to the Indian Pharmacopoeia Commission (IPC) Ghaziabad. Following are the objectives of PVPI [26].

- To establish a nationwide structure for patient safety reporting.
- To pinpoint and examine the new ADR from the report.
- To examine the benefit-risk ratio of drugs that is in the market.
- To assist regulatory agencies in the decision-making process on the use of medicine.
- To appear as a national centre for pharmacovigilance activities.
- To produce the proof-based information on the safety of medicine.
- To cooperate with other centres for sharing the information and to manage the data.

- To give training and support to other national pharmacovigilance Centres located worldwide [27].

PVPI regularly run a skill learning programme for pharmacists, doctor and nurses. Currently, 250 adverse drug monitoring centres have been set up countrywide in the different government hospital and medical institution. Out of all centres PGIMER Chandigarh reported the maximum number of ADR reports, followed by MMC, Chennai [28]. The evaluation of causality is performed jointly by the ADR monitoring centre and NCC (National Co-ordination Centre). PVPI programme has a well-established panel for reviewing signals. According to the WHO signal is "The information reported that have chances to be casually link between an adverse event and drug, this relationship is not known previously and not documented elsewhere [29]. The PVPI time to time creates an alert for the detected signal. Following are some goals of PVPI:

- To develop own database on ADR.
- To establish pharmacovigilance in all hospitals and centers situated nationwide.
- To advance reporting through an electronic system.
- To uplift reporting tradition among medics.
- To make ADR reporting compulsory for other institutions.
- To collect all the case reports and data management.

Data flow

Two ADR forms are sent to the coordinating centre one after collecting by AMC staff. The record of ongoing activities is maintained by AMC staff, few AMC can execute ADR monitoring of drugs. The data is then uploaded to PV database; the coordinating centre makes up a merged ADR report from different ADR report fetched between a time intervals. Finally, the combined data is uploaded in Vigiflow into the Uppsala database, and signal detection is performed (Figure 2).

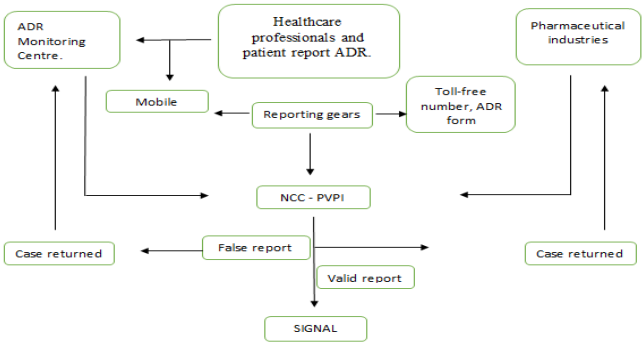

Figure 2: Procedure of ADR reporting.

Why PV is not expanding in India

New drugs are introduced into India as the market is widespread and large when compared to other small countries. So, the need for pharmacovigilance is more in India, however there are many problems due to which PV is lacking in India.

Some of the issues are as follow

- Lack of funds in the PV programme.
- Awareness among public and healthcare professionals is lacking.
- Physician centered healthcare system.
- Poorly reported data and imperfection in the analysis of data.

DISCUSSION

A successful pharmacovigilance program related to drug safety should answer important questions. How early were incidents identified? And what percentage of patients was successfully monitored collectively by physicians, pharmacists/healthcare professionals?

The challenges associated with pharmacovigilance programs in India can be avoided through strict enforcement of appropriate rules and regulations everywhere. Strengthen public campaigns on drug safety to raise awareness, add drug safety research to the curriculum, and minimize the magnitude of side effects through solid knowledge of drug side effects. This is because the number of drugs increasing daily can benefit pharmacovigilance programs.

CONCLUSION

This overview focuses on how the pharmacovigilance completely shifts after the thalidomide incidence. Pharmacovigilance is very crucial as its main aim is to provide patients on safe, rational and pocket-friendly treatment. However low rate of reporting, low funding by the government, physician centered healthcare are some of the issues that have to the eliminated. Especially in developing countries where there is additional risk in using a medicine.

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