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Review Article

PHARMACOVIGILANCE: AN EMERGING FIELD

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Abstract:

Pharmacovigilance is instrumental in helping to ensure patient safety for both newly released drugs and those that are well established in the market. It 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. Despite its 40 years history, Pharmacovigilance remains a dynamic clinical and scientific discipline. It continues to play a crucial role in meeting the challenges posed by the ever increasing range and potency of medicines. When adverse effects and toxicity do appear especially, when previously unknown, it is essential that these are reported, analysed and their significance communicated effectively to an audience that has the knowledge to interpret the information, which carry an inevitable and some for all medicines there is a trade-off between the benefits and the potential for harm. The harm can be minimized by ensuring that medicines of good quality, safety and efficacy are used rationally and that the expectations and concerns of the patient are taken into account when therapeutic decisions are made.

Key Words: Adverse Effects, Efficacy, Pharmacovigilance, Toxicity, Medicines

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INTRODUCTION:

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 [1]. The etymological roots for the word "pharmacovigilance" are: *pharmakon* (Greek for drug) and *vigilare* (Latin for to keep watch). As such, pharmacovigilance heavily focuses on adverse drug reactions, or ADRs, which are defined as any response to a drug which is noxious and unintended, including lack of efficacy (the condition that this definition only applies with the doses normally used for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological disorder function was excluded with the latest amendment of the applicable legislation)[2].

Pharmacovigilance involves consumers, health care professionals (HCPs), pharmaceutical companies, and global regulatory agencies, each of whom plays a unique and critical role in this process. Generally speaking, pharmacovigilance is the science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medications, biological, herbalism and traditional medicines with a view to:

- Preventing harm from adverse reactions in humans arising from the use of authorised medicinal products within or outside the terms of marketing authorization or from occupational exposure and
- Promoting the safe and effective use of medicinal products, in particular through providing timely information about the safety of medicinal products to patients, healthcare professionals and the public.
- Identifying new information about hazards associated with medicines [3].

The satisfactory reimbursements and hazards possessed by the drug at the time of approval of a new drug are decided on the basis of the recent data available. New information will be generated when drug is marketed which may have an effect on the advantage and disadvantage profile of the product. To ensure safe use of the drug, the thorough assessment of the new evidence generated through pharmacovigilance activity is needed. At the pre-clinical and clinical testing stages of the new product when prescribed to huge inhabitants there is no safety of that product. The impacts of Pharmacovigilance on the life cycle of the product is needed to understand, that can be achieved by more and more clinical trials and other clinical research activities being conducted

in India [4]. In new class of all drugs, continuous observing and evaluation is required under the real-world conditions on the side effects and contraindication a strong Pharmacovigilance system is required. The products which are already approved and marketed in the delimited markets of Japan, USA, Europe or other countries Indian market has mostly launch only those products. In 1986 a formal adverse drug reaction (ADR) monitoring system consisting of 50 million populations was covered by 12 regional centers, so Pharmacovigilance is not new to India. Uppsala Centre for Adverse Event Monitoring joined by India from 1998, great achievements were made during this retro, but much more still needs to be done in this field in India. Day by day, the importance of pharmacovigilance is increasing and with recent high-profile drug withdrawals was done from markets the regulatory agencies, consumers and others because the value of Pharmacovigilance increased and people become more aware about the advantage and hazards of medicines [5].

HISTORICAL PERSPECTIVES OF WHO - DRUG SAFETY MONITORING:

It was not until 1986 that a formal adverse drug reaction (ADR) monitoring system consisting of 12 regional centres, each covering a population of 50 million, was proposed for India[6]. In 1997, India joined hands with the World Health Organization (WHO) Adverse Drug Reaction Monitoring Programme based in Uppsala, Sweden. Three centres for ADR monitoring were identified, mainly based in teaching hospitals: A National Pharmacovigilance Centre located in the Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), New Delhi and two WHO special centres in Mumbai (KEM Hospital) and Aligarh (JLN Hospital, Aligarh Muslim University). These centres were to report ADRs to the drug regulatory authority of India. The major role of these centres was to monitor ADRs to medicines which are marketed in India. However, they hardly functioned as information about the need to report ADRs and about the functions of these monitoring centres were yet to reach the prescribers and there was lack of funding from the government. This attempt was unsuccessful and hence, again from the 1st of January 2005, the WHO- sponsored and World Bank-funded National Pharmacovigilance Program for India was made operational [7].

In 2002, more than 65 countries have their own pharmacovigilance centers. Membership of the WHO for International Drug Monitoring is coordinated by the WHO Collaborating Centre for International Drug Monitoring, known as the Uppsala Monitoring Centre (UMC). Pharmacovigilance is now firmly

based on sound scientific principles and is integral to effective clinical practice. The discipline needs to develop further to meet public expectations and the demands of modern public health. The Sixteenth World Health Assembly adopted a resolution (WHA 16.36)[5] that reaffirmed the need for early action in regard to rapid dissemination of information on adverse drug reactions and led later to creation of the WHO Pilot Research Project for International Drug Monitoring. The purpose of this was to develop a system, applicable internationally, for detecting previously unknown or poorly understood adverse effects of medicines [8].

Table 1: The sequential pharmacovigilance developments with special reference to India [1,9,10]

YEAR	DEVELOPMENTS
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	Apalstic 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	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
2009-10	Pharmacovigilance Program (PvPI) started.

Aim of Pharmacovigilence [11]

- ✓ Improve patient care and safety in relation to the use of medicines, all medical and Para medical interventions.
- ✓ Research the efficacy of drug and by monitoring the adverse effects of drugs right from the lab to the pharmacy and then on for many years.
- ✓ Pharmacovigilance keeps track of any drastic effects of drugs.
- ✓ Improve public health and safety in relation to the use of medicines.

- ✓ Contribute to the assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more effective (including cost effective) use.
- ✓ Promote understanding, education, clinical training in pharmacovigilance and its effective communication to the public.

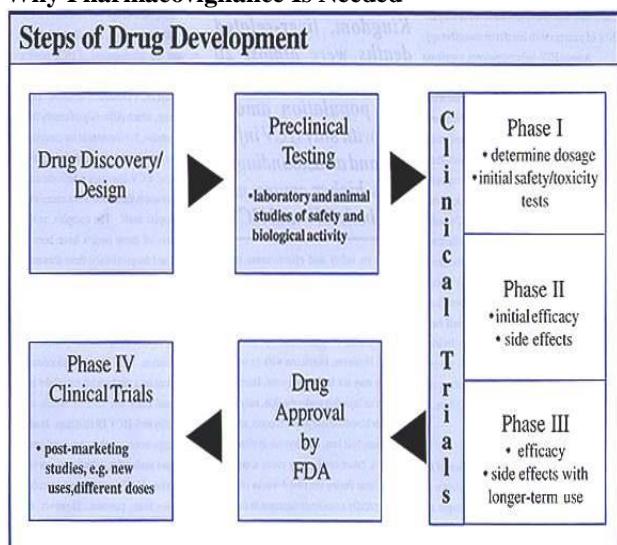
These processes involved in the clinical development of medicines. Once put onto the market, a medicine leaves the secure and protected scientific environment of clinical trials and is legally set free for consumption by the general population. At this point most medicines will only have been tested for short-term safety and efficacy on a limited number of carefully selected individuals. In some

Table 2: Classical example of serious and unexpected adverse reactions

Medicine	Adverse reaction
Aminophenazole (amidopyrine)	Agranulocytosis
Chloramphenicol	Aplastic anaemia
Clioquinol	Myelooptic neuropathy
Erythromycin estolate	Cholestatic hepatitis
Fluothane	Hepatocellular hepatitis
Methyldopa	Haemolytic anaemia
Oral contraceptives	Thromboembolism
Practolol	Sclerosing peritonitis
Reserpine	Depression
Statins	Rhabdomyolysis
Thalidomide	Congenital malformations

cases as few as 500 subjects, and rarely more than 5000, will have received the product prior to its release¹⁰. For good reason, therefore it is essential that new and medically still evolving treatments are monitored for their effectiveness and safety under real-life conditions post release. More information is generally needed about use in specific population groups, notably children, pregnant women and the elderly and about the efficacy and safety of chronic use, especially in combination with other medicines. Experience has shown that many adverse effects, interactions (i.e. with foods or other medicines) and risk factors come to light only during the years after the release of a medicine.

Why Pharmacovigilance Is Needed [11]



The processes involved in the clinical development of medicines are illustrated in Figure 1. Once put onto the market, a medicine leaves the secure and protected scientific environment of clinical trials and is legally set free for consumption by the general population. At this point, most medicines will only have been tested for short-term safety and efficacy on a limited number of carefully selected individuals. In some cases as few as 500 subjects, and rarely more than 5000, will have received the product prior to its release. For good reason, therefore, it is essential that new and medically still evolving treatments are monitored for their effectiveness and safety under real-life conditions post release. More information is generally needed about use in specific population groups, notably children, pregnant women and the elderly, and about the efficacy and safety of chronic use, especially in combination with other medicines. Experience has shown that many adverse effects, interactions (i.e. with foods or other medicines) and risk factors come to light only during the years after the release of a medicine (see Table 2).

Over the last decade, it has been increasingly recognized that the scope of Pharmacovigilance needs to be extended beyond the strict confines of detecting new signals of safety concerns. Globalization, consumerism, the resulting explosion in free trade and communication across borders, and increasing use of the Internet have all contributed to a change in the way people access medicinal products and information about them. These changing patterns in drug use require a shift in the approach to pharmacovigilance, more specifically, towards one that is more closely linked, and thus better able to respond, to the prevailing patterns of drug use within society.

PARTNERS IN PHARMACOVIGILANCE [12]

The management of the risks associated with the use of medicines demands close and effective collaboration between the key players in the Pharmacovigilance. Sustained commitment to such collaboration is vital if the future challenges in Pharmacovigilance are to be met, and if the discipline is to continue to develop and flourish. Those responsible must jointly anticipate, describe and respond to the continually increasing demands and expectations of the public, health administrator policy officials, politicians and health professionals. However, there is little prospect of this happening in the absence of sound and comprehensive systems which make such collaboration possible. The constraints typically include lack of training, resources, political support, and most especially scientific infrastructure. Understanding and tackling these are an essential prerequisite for future development of the science and practice of pharmacovigilance. Monitoring the safety of medicines: key partners

- Government
- Industry
- Hospitals and academia
- Medical and pharmaceutical associations
- Poisons and medicines information centres
- Health professionals
- Patients
- Consumers
- The media
- World Health Organization

Most Frequently Used Methods For Monitoring Of Drug Safety Are As Follows [13-16]:

Spontaneous reporting systems (SRSs)

Spontaneous reporting systems involve the recording and reporting clinical observations of a suspected Adverse Drug Reactions (ADRs) with a marketed drug. It is also known as spontaneous or voluntary reporting. There are slight differences in this reporting system among the various countries but the ideology are the same. Safety of medicines is frequently monitored through spontaneous reporting systems (SRSs) [17,18]. Moreover the standardized forms are used for reporting of alleged adverse drug reactions to the regulatory system by physicians, pharmacists, nurses and consumers as well [13,19].

Prescription-event monitoring (PEM)

Prescription-event monitoring (PEM) is an observational cohort and non interventional form of pharmacovigilance. Prescription-event monitoring (PEM) studies are cohort studies in which exposure is collected from a centralized service and outcomes from simple questionnaires finished by general

practitioners. Moreover the follow-up forms are used for selected Adverse Events (AE). Prescription-event monitoring (PEM) captures all Adverse Events (AE) and the alleged drug reactions (ADRs). [17][18] Prescription-event monitoring (PEM) cohorts potentially are different in deference to the distribution of number of Adverse Events (AE) per person depending on the character of the drug under study [13,19].

National pharmacovigilance system- India

India attached with the World Health Organization's (WHO) Adverse Drug Reaction (ADR) Monitoring Programme based in Uppsala, Sweden in the year 1997. In India, for the monitoring of Adverse Drug Reaction

(ADR's) there were three main centres identified: [20,21]

1. A National Pharmacovigilance Centre in the Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), New Delhi.
2. WHO special centers in Mumbai (KEM Hospital).
3. Jawahar Lal Nehru Hospital, Aligarh Muslim University, Aligarh [22,23].

The mentioned centers monitor the Adverse Drug Reactions (ADRs) of the drugs available in market for sell on OTC counter [17]. This effort was ineffective and then second time from the 1st of January 2005, the WHO sponsored and World Bank funded National Pharmacovigilance Program for India was established [13]. The National Pharmacovigilance Program (PvPI) recognized in January 2005, and supervised by The Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services under the aegis of Ministry of Health & Family Welfare, Government of India in collaboration with Indian Pharmacopeia commission, Ghaziabad [13]. Two zonal centers-KEM located in the Department of Pharmacology, AIIMS, New Delhi and the South-West zonal centre located in the Department of Clinical Pharmacology, Seth GS Medical College [13,14] Meanwhile established information centres which collate information from all over the country and send it to the Committee as well as to the Uppsala Monitoring centre in Sweden [20,23].

ADVERSE EVENT:

An adverse event is not having any causal relationship with patient treatment but its one of the medical incidence with patient. So an adverse event (AE) can be any critical or Unintentional indication of disease which is temporally related with the use of a medication [25,26] **Fig 2**.

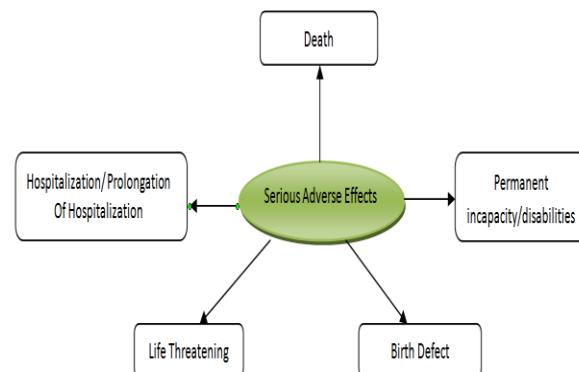


Fig2: Chart for Adverse Event

ADVERSE DRUG REACTION:

At a normal dose sometimes the given medications may harm the patients which are called as an **adverse drug reaction (ADR)** [5]. Meaning of adverse drug reaction is different from side effect. The evaluation of ADRs is most critical in the field of pharmacovigilance. Concerning marketed remedies, a suitable definition of an adverse drug reaction is as follows: In patient at normal doses harmful and unpleasant reaction of drug for treatment and medication of disease or for changes of biological utility. Mainly two types of adverse drug reaction which are as follows [26].

1. Unlisted / Unexpected Adverse Drug Reaction

An adverse reaction is the nature or harshness of drug which is not reliable with the proper product data which available at the time of the clinical trials.

- Company is needed help during investigators brochure for an unapproved drug
- Brief summary of drug data sheet for an official product.

2. Listed / Expected Adverse Drug Reaction

The information about ADR its like nature or severity and specificity of the drug is already recorded [26].

STEPS INVOLVED IN STUDY

Adverse drug reactions can occur when the body's immune system reacts with the chemical compound in a drug, report doctors at the American Academy of Family Physicians. Other reactions happen as result of allergies. Unknown causes of adverse drug reactions can happen when a diagnosis is not clear or a patient's medical history is in question. While treatment usually involves discontinuing the offending drug, you need to know the best way report adverse drug reactions to receive the proper treatment.

Step 1: Keep the prescription bottles of your medications so healthcare providers can get the exact name of the drug that you are taking when you have a reaction. AAFP doctors report that most drug reactions manifest as a rash, but can be severe and cause unconsciousness.

Step 2: Be prepared to report any allergic reactions you may have had in the past to help doctors diagnose your symptoms. Keep a record of when you started taking a new medication. Have available a list of all medications you are currently taking, including the dosage amount. Android Developer CPM's Earn Over 10x Higher with our Android SDK. www.airpush.com Sponsored Links

Step 3 :Show treating physicians any skin rash or other skin abnormality. You may have a fever and trouble breathing, but any number of factors could account for those symptoms. When combined with a skin discoloration or lesion, an adverse drug reaction diagnosis is easier to make.

Step 4: Document the treatment you received that caused the reaction as well as the results. Keep track of dates, medical complications you underwent, the level of your reaction and how you were treated so you can follow up with the proper reporting procedures if your doctor refuses to report your reaction.

Step 5: Print the Food and Drug Administration reporting form from the FDA website and bring it to your doctor to fill out. If you prefer not to go through your healthcare provider, the FDA does accept reports of adverse drug reaction from consumers. This is a voluntary program that is monitored by the FDA to follow patients' experiences with various medications.

Step 6: Call the FDA at (800) FDA-0178 if you do not have access to online reporting. Use the FDA to report fraud or misuse of drugs as well as adverse reactions to prescribed medication, medical devices or over-the-counter medications or supplements

FUTURE PROSPECTS [28,29]

Pharmacovigilance has been expanding in recent years, as companies are required to monitor drug safety post launch. Drug safety issues, such as those raised by Vioxx earlier this decade, have led to increased risk-averseness by regulators, with greater post-marketing assessment of drugs. Many regulatory agencies require detailed pharmacovigilance, with companies bearing extra costs, our new report also observes. Healthcare payers, prescribers and patients have high expectations from pharmacovigilance. They want thorough information - on adverse reactions and overall drug safety -upon which to make informed judgements. Pharmacovigilance is now being called upon to produce clear results,

expressed openly. What will those trends mean for pharmacovigilance, from the perspectives of major stakeholders, including the pharma and biotech industries? Where is pharmacovigilance heading? What regulatory measures will continue, and which new processes will emerge? This new report - Pharmacovigilance 2009: Present Challenges and Future Goals- explains how that field will develop from the present onwards. Clearly, pharmacovigilance is increasingly important worldwide, especially to avoid reoccurrences of serious, costly problems damaging to the industry. Pharmacovigilance is designed to provide crucial data on how drugs work in medical practice, from the short-term to the long-term. This information can aid drug development and marketing if harnessed properly, being a boon rather than a hindrance. In particular, visiongain believes that live licensing will form a significant part of pharma regulations and drug development in coming years. Pharmacovigilance will underpin processes and developments such as these, as this report further explains. Medicines have helped to bring improved health and longer life to human beings. Medicines affect the lives of hundreds of millions of people every day. But they are not without risk, and have caused, do cause and will continue to cause harm to many people. There are also large numbers of people who experience no evident effect at all from the drugs they take. To be eternally vigilant to ensure that medicines, which are developed for treatment of diseases, actually do not do more harm than good, is one of the important pre-requisites for the progress of medicine.

CONCLUSION:

Pharmacovigilance remains a dynamic clinical and scientific discipline. It continues to play a crucial role in meeting the challenges posed by the ever increasing range and potency of medicines, all of which have unpredictable potential for harm. When adverse effects and toxicity do appear especially when previously unknown it is essential that these are reported, analysed and their significance communicated effectively to an audience that has the knowledge to interpret the information. Which carry an inevitable and some-for all medicines there is a trade-off between the benefits and the potential for harm. The harm can be minimized by ensuring that medicines of good quality, safety and efficacy are used rationally, and that the expectations and concerns of the patient are taken into account when therapeutic decisions are made.

To achieve this is to:

- Serve public health, and to foster a sense of trust among patients in the medicines they use

that would extend to confidence in the health service in general;

- Ensure that risks in drug use are anticipated and managed;
- Provide regulators with the necessary information to amend the recommendations on the use of the medicines;
- Improve communication between the health professionals and the public;
- Educate health professionals to understand the effectiveness/risk of medicines that they prescribe. This is the important role of pharmacovigilance

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