

Title : A Review On Pharmacovigilance: Safeguarding Health Through Drug Safety Monitoring.

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Abstract

The WHO PIDM in Focus - Building a global community Since it was established in 1968, the WHO Programme for International Drug Monitoring (WHO PIDM) has sought to put medicines and vaccine safety at the heart of global healthcare. UMC's role in education and training, the development of pharmacovigilance tools, and as the custodian of VigiBase – the WHO global database of adverse event reports for medicines and vaccines – is integral to the WHO PIDM. For almost 50 years, UMC has worked side by side with WHO to fulfil its mission, putting patient safety front and centre. This film tells that story

Drugs safety profile monitoring is an essential element for the effective use of medicines and for high quality medical care. Pharmacovigilance (PV), is the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products. The PV comes in picture after elixir sulfanilamide tragedy of 1937 and in the late 1950s and early 1960s, more than 10,000 children in 46 countries were born with deformities such as phocomelia as a consequence of thalidomide use has opened the eyes of drug regulators as well as consumers to establish a way to ensure drug safety. The hospitalization due to adverse drug reaction (ADR) in USA is about or more than 10%. In addition, it is estimates that 15- 20% of the hospital inpatient suffers from ADRs. Now the pharmacovigilance system is globalised, strengthen and systematized after the establishment of World Health Organization (WHO) Programme for International Drug Monitoring. The patient safety is now becoming the priority area of pharmaceuticals. In this article, we are describing brief history and introduction of PV that will help to understand PV for beginners

Medicines and vaccines have transformed the prevention and treatment of diseases. In addition to their benefits, medicinal products may also have side effects, some of which may be undesirable and / or unexpected. Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem.

All medicines and vaccines undergo rigorous testing for safety and efficacy through clinical trials before they are authorized for use. However, the clinical trial process involves studying these products in a relatively small number of selected individuals for a short period of time. Certain side effects may only emerge once these products have been used by a heterogenous population, including people with other concurrent diseases, and over a long period of time.

Keywords

Pharmacovigilance, Adverse drug reaction monitoring, Clinical trial

Introduction

An important part of clinical research starting from drug discovery. The drug discovery is mainly based on preclinical and clinical trails

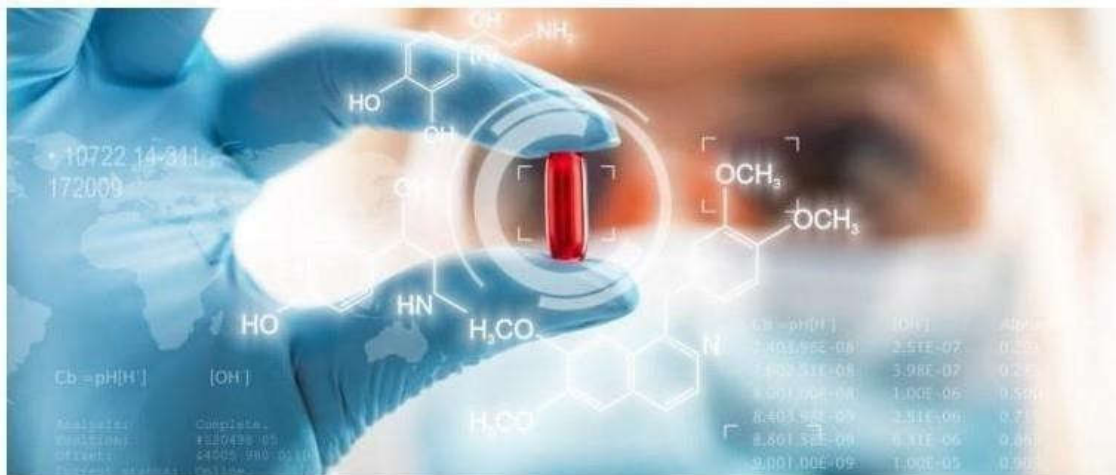


Fig No.1

According to WHO, Pharmacovigilance can be defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. The Central Drugs Standard Control Organization (CDSCO), New Delhi, under the aegis of Ministry of Health and Family Welfare (MOHFW) has initiated the PvPI in July 2010. Initially National coordinating centre (NCC) was AIIMS, New Delhi but it was shifted to Indian Pharmacopoeia commission (IPC), Ghaziabad (U.P.) in April 2011. The vision of PVPI is to improve patient safety in Indian population by monitoring drug safety and there by reducing the risks associated with the use of medicines.

Adverse drug reaction Monitoring Centres (AMCs) play a vital role in PvPI. These AMCs include MCI approved medi cal colleges and hospitals, autonomous institutes and even corporate hospitals. AMCs are responsible for collecting the ADR (adverse drug reaction) reports from patients and sending it to NCC via entry in a software called Vigiflow. NCC then assesses the ICSR (individual case safety reports) by various methods of causality assessment like Naranjo scale, and if found valid will commit to Uppsala Monitoring centre (UMC) in sweden.

patients should be evaluated in order to assess the risk and benefits involved with respect to a particular drug.



Fig no.2

A careful monitoring of drug usage at every step such as pharmacovigilance inspection, reporting of ADR, periodic collection of safety report, post-authorization safety studies is required. The information technology supports very effectively for development of health -care industry. In fact, clinical safety practices have improved by strong support of IT. Thus, safety, efficacy, and cost reduction of drugs are very much important. Presently pharmacovigilance plays very critical role in drug development process. There are various methods to identify the problems related to the use of medicines. The studies of prescription events monitoring or thorough and careful review of adverse drug reactions in hospitalized patients or patients discharged from the hospital are covered under the active pharmacovigilance. Passive pharmacovigilance depends mainly on spontaneous reporting. During clinical practice the health care professionals are supposed to report the adverse drug reactions to the pharmacovigilance team. Some of these methods are considered as pharmacoepidemiological tools. Study of use and effects of drugs on large number of population is called

pharmacoepidemiology. This is most important for post marketing evaluation of drugs. Due to

evolution of epidemiological methods and changes in the definition of ADRs, or due to variation in marketing and promotional techniques, pharmacovigilance and pharmacoepidemiology sciences have become complementary to each other. Out of all the methods in pharmacovigilance spontaneous reporting is the most traditional one and is considered as the foundation method for post-marketing surveillance.

Objectives

- To monitor Adverse Drug Reactions (ADRs) in Indian population
- To create awareness amongst health care professionals about the importance of ADR reporting in India
- To monitor benefit-risk profile of medicines
- Generate independent, evidence based recommendations on the safety of medicines
- Support the CDSCO for formulating safety related regulatory decisions for medicines
- Communicate findings with all key stakeholders
- Create a national centre of excellence at par with global drug safety monitoring standards
- To improve patient care and safety
- To improve public health and safety
- To contribute to the assessment of benefit, harm, effectiveness and risk of medicines
- To promote understanding, education and clinical training
- To create a nation-wide system for patient safety reporting
- To identify and analyse the new signal (ADR) from the reported cases
- To analyse the benefit-risk ratio of marketed medications
- To generate the evidence based information on safety of medicines
- To support regulatory agencies in the decision-making process on use of medications
- To communicate the safety information on use of medicines to various stakeholders to minimise the risk
- To emerge as a national centre of excellence for pharmacovigilance activities
- To collaborate with other national centres for the exchange of information and data management

Scope of Pharmacovigilance

It has relevance on the suspicion of ADRs sent by the clinicians and subsequent analysis of the reports by physicians, clinical pharmacologists, and practicing pharmacists.

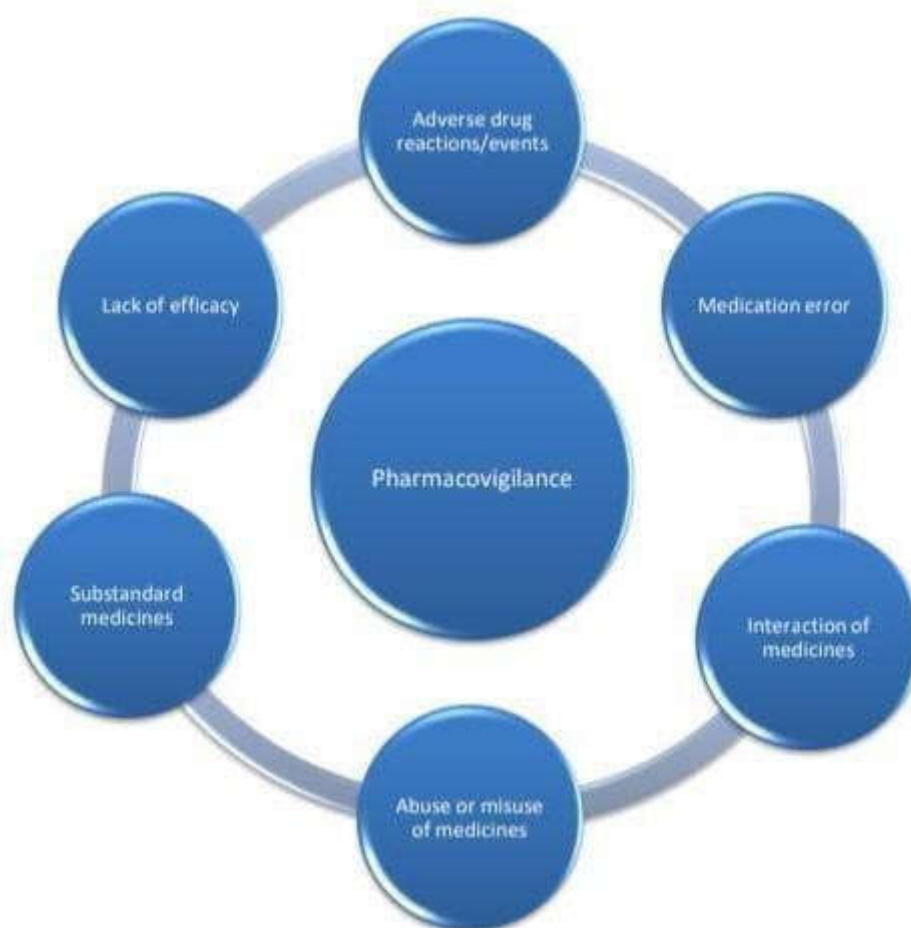


Fig no.3

Types And Components of Pharmacovigilance

Clinical

The International Conference on Harmonization defines a clinical trials as,"Any investigation in humans subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product, and/or to identify any ADR to an investigational drugs, and/or to study ADME of drug with the objective of ascertaining the safety and efficacy. This is also termed as randomized control trial Clinical trials are a set of procedures in medical research conducted to allow safety and efficacy data to be collected for health interventions.



Fig no.4

Pharmacovigilance is involved in the safety of medicines during clinical trials. BSV conducts clinical trials at various Hospitals and centres in India and other geographies and countries to evaluate the safety and efficacy of the company's medicinal products. These clinical trials help in the development of medicines that may benefit people and help find new treatments for different health conditions.

The company prioritizes the rights, safety, and well-being of trial participants who voluntarily consent to participate in BSV sponsored clinical trials. All studies involving human volunteers and patients are carried out in accordance with applicable laws, guidelines, rules, regulations, and policies for the conduct of clinical trials, including

Good Clinical Practices (GCP) standards. All clinical trials conducted by BSV are registered prospectively in the Clinical Trial Registry of India (CTRI) and other applicable registries e.g., clinicaltrials.gov etc.

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Clinical trials are studies conducted on human volunteers who consent to participate in such studies. These clinical trials are to evaluate the safety and effectiveness of medicinal products, medical devices, vaccines, other biologic therapies, and further may also include assessment of new indications for use of already approved medicinal treatments.

Why are Clinical Trials needed?

Clinical trials are required to evaluate potential new treatments in human volunteers and patients to assess whether they should be approved for wider use in the population affected by the specific medical condition(s). A treatment could be a medicinal product, a medical device, a vaccine, or any other biologic therapy.

ICH-GCP E6 (R2) Guidelines (2016), New Drugs & Clinical Trial Rules, INDIA (2019), National Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR (2017) are the guidelines and laws that govern clinical trials in India.

At BSV, we acknowledge the contribution of study participants as well as healthcare professionals (Clinical trial investigators and research staff at Hospital and centres where clinical trials are conducted) who collaborate with us in the company sponsored clinical trials which often address medical needs in important health conditions.

It includes number of Phases.

1. Phase 0 trials :- (Microdosing studies)
2. Phase 1 trials :- (Human Pharmacology)
3. Phase 2 trials :- (Therapeutic exploratory)
4. Phase 3 trials :- (Therapeutic confirmatory)
5. Phase 4 trials :- (Post Marketing Surveillance)

Phase 1 :- Here, the drug is tested in normal human volunteers (extremes of ages; elderly and children are excluded). As the drug is not tested in the patients, so we cannot determine efficacy

in this phase. This is mainly for toxicity and pharmacokinetic studies. This is first in human study. The idea of testing the new drug in normal humans is based on the fact that healthy persons are more likely to tolerate the adverse effects of the drug than diseased persons. Because anti-cancer drugs can produce unacceptable toxicity and we cannot expose healthy humans to such a toxicity, the phase-1 trials for anticancer drugs are done in the patients. Phase

2 :- The drug in this phase is tested in small number of (20-200) patients. We can determine both efficacy and safety in this phase. This is first in patient study.

Phase 3 :- Here the drug is tested in large number of patients at several centers to include patient with different genetic makeup. This is done to generalize the results of the study to variable genetic and ethnic groups. If the drug is found to be safe and effective in these trials, then another application is filed with FDA (New Drug Application or NDA) to market the drug. If approval is granted, the drug is marketed.

Phase 4 :- This is post marketing surveillance of a drug to know the rare adverse effects or those occurring with prolonged use of the drug. In this phase ethical clearance is not required. Phase 0 :- These are also called microdosing studies. Here, a very low dose 1/100th of human dose; maximum 100 µg) of the drug is administered to healthy volunteers. As the dose is subtherapeutic, so safety and efficacy cannot be known in phase 0. However, the drug is radiolabelled and thus movement of drug in the body can be known. This could avoid costly phase I studies for candidate drugs with unsuitable pharmacokinetics. All phases of clinical trials must follow the ICH-GCP (Good clinical practice guidelines given by International Conference for Harmonization, so that the data generated is credible and interest of the patients can be safeguarded

Showing a comparison of microdosing strategy and conventional studies

<i>Features</i>	<i>Microdosing strategy</i>	<i>Conventional approach</i>
Time from preclinical to first in man studies	6-8 months	12-18 months
Cost of early phase of drug development	US\$ 0.3 -0.5 million	US\$ 1.5-5.0 million
Amount of drug required	<100 micrograms	About 100 grams
Special requirements	C14 labeled compound, if using AMS	None required
Regulatory requirements	Very few and limited	Established firmly

Fig no.5

Pre-Clinical

Its is based on a laboratory test of a new drug or a new medical device, usually done on animal subjects, to see if the hoped-for treatment really works and if it is safe to test on humans. Many preclinical tests include pharmacokinetics - the study of how drugs move through living organisms. Four processes are examined in pharmacokinetic studies: absorption, distribution, metabolism,& excretion .

Before a new drug comes to the market, it is extensively tested in animals and in vitro studies for safety and efficacy. If th drug is found to be promising in these studies, an Application called IND (Investigational New Drug) is filed with th United States Food and Drug Administration (main regulatory authority). If the permission is granted, then drug is tested in humans. This testing is called clinical trials.

Initially, Animals studies are performed to define the pharmacological profile of the lead compound the aim during the preclinical phase of development is to satisfy all the requirement that are needed before a compound is considered fit to be tested for first time in human.

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Fig no.6

- Especially the toxicological studies, is done according to the standard laid down in a formal operating code known as "GOOD LABORATORY PRACTICES"

-This ensures reliability and reproducibility of laboratory data and minimizes human errors.

Out of the 10,000 compound screened during drug discovery phase, only 10 qualify the phase of preclinical evaluation which are then subjected to clinical trials in humans.

Pre And Post Marketing Clinical Trails

Pharmacovigilance system studies the long term and short term adverse drug reaction or simply stated- side effects of medicines. Pharmacovigilance system involves collection, monitoring, researching upon, assessing and evaluating information received from health care workers such as doctors, dentists, pharmacists, nurses and other health professionals for understanding the adverse drug reaction. Pharmacovigilance definition includes monitoring of all pharmaceutical drugs and also other medical products including vaccines, X-ray

contrast media, traditional and herbal remedies etc. especially when the reaction is unusual, potentially serious or clinically significant.

Pre-marketing clinical trials vs. Post-marketing monitoring

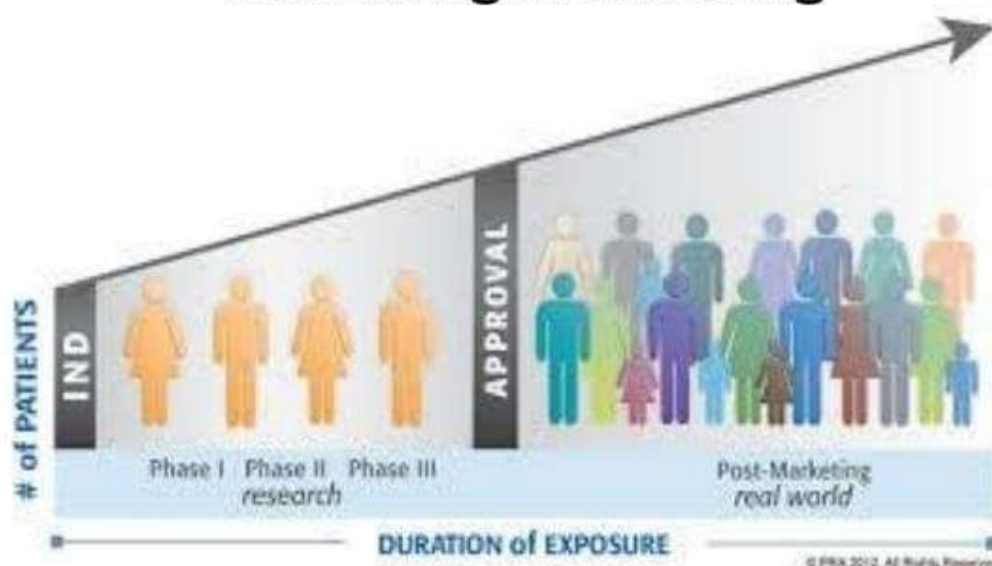


Fig no.7

These trials are conducted before a drug is approved for marketing, while post-marketing clinical trials are conducted after a drug is approved. The trials are conducted in a controlled setting with a small number of patients to evaluate the safety and efficacy of a drug. They include phase-1, phase-3 trials, dose ranging studies, and randomized controlled trials.

Pre-marketing clinical trials

Safety monitoring in clinical trials involves collecting adverse events, laboratory investigations and details of the clinical examination of patients. Pharmacovigilance staff may be involved to varying degrees in all phases of clinical trials, including the planning, execution, data analysis and reporting of safety information. Safety issues from animal pharmacology and toxicology studies, findings in phase I studies, known ADRs with similar drugs, signals from other studies and special patient groups, (e.g. the elderly) need to be addressed.

The practice of collecting all adverse events rather than suspected ADRs arose from the failure of clinical trials to detect serious reactions with practolol and after several years experience this is now the approach adopted by companies in most studies. The involvement of pharmacovigilance staff in clinical trials also includes an important responsibility for the expedited reporting of individual cases and safety updates required by the UK Medicines Control Agency (MCA) and other regulatory authorities.

Clinical studies (Pre-marketing studies)

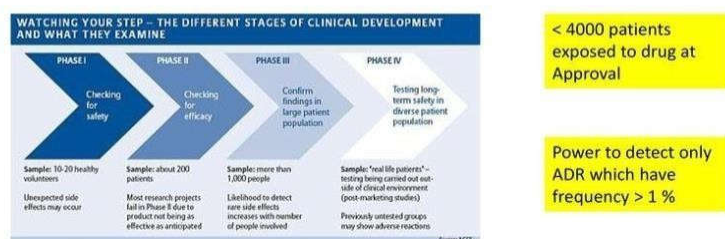


Fig no.8

Well conducted clinical trials should be able to identify and characterize Common type A (pharmacologically mediated) ADRs, indicate how these are tolerated by patients, determine a relationship between ADRs and dose or plasma concentration and identify pre-disposing (risk) factors if at all possible.

These issues will usually be presented and discussed in an integrated safety analysis and clinical expert report in the Marketing Authorisation Application submitted by the company and will be the basis of ADRs, warnings and precautions included in the prescribing information i.e. Summary of Product Characteristics (SPC) or data sheet.

However, clinical trial programmes before marketing are limited in their power to detect rare, particularly type B (non-pharmacologically mediated) ADRs. This is because of the limited number of patients that are studied before marketing, the frequent exclusion of patients who may be at greater risk e.g. the elderly and those with significant concurrent disease, and the structured nature of clinical trials where drugs are given at specific doses for limited periods of time by experienced daily

routine clinical practice and possibly in larger studies will the less common ADRs and other 'at risk' groups be identified. Post-marketing surveillance (PMS) by companies is therefore essential.

Spontaneous reporting

Recording and reporting clinical observations of a suspected ADR with a marketed drug is known as spontaneous or voluntary reporting. The national system in the UK is the 'yellow card' scheme where doctors, dentists, and recently, hospital pharmacists are encouraged to report all suspected reactions to new medicines and serious suspected reactions to established medicines. Pharmaceutical companies also collect and collate such reports with their licensed products. Reports to companies often come initially as a question from a prescribing physician or pharmacist to Medical Information or a sales representative about whether a product could be the cause of a patient's problem.

After providing such information, pharmacovigilance staff will seek details of the case to add to the database of reports; this relies on the goodwill and continued interest of reporters.

Companies must report suspected ADRs to the MCA and other authorities; some authorities, including MCA, make anonymised data available to licence holders. There is also a move towards electronic exchange of data between authorities and companies.

The culture of reporting varies greatly between countries in terms of the quantity, quality and source of reports. In the UK and Sweden most doctors report directly to the national regulatory authority rather than pharmaceutical companies, although some report to both. In other countries such as Germany and the USA the majority of reports go initially to companies who then report to the authority in that country. The proportion of reports received by companies directly from patients also varies considerably between countries and is highest in the USA.

Spontaneous reporting has advantages in that it is available immediately a new product is marketed, continues indefinitely and covers all patients receiving the drug. It is the most likely method of detecting new, rare ADRs and frequently generates safety signals which need to be examined further. The main limitations are the difficulty in recognising previously unknown reactions, particularly events that are not

usually does not confirm hypotheses; although situations exist where spontaneous reporting data alone allow conclusions that a signal indeed represents a true ADR, see ‘using spontaneous reporting data for hypothesis testing’ below.

Signal management

This is an important process in pharmacovigilance that can be performed using traditional or automated systems. Automated systems are generally more advantageous than manual process.

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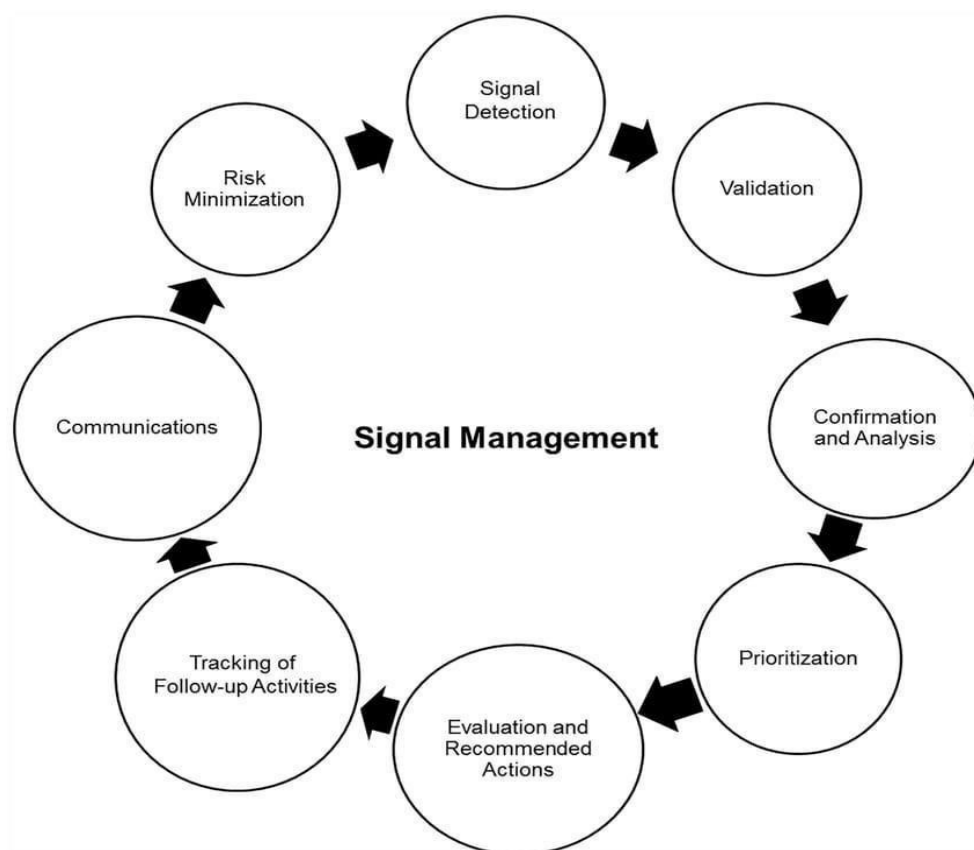
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Pharmacovigilance Signal Management in Pharmacovigilance

A safety signal is information on a new or known adverse event that is potentially caused by a medicine and that warrants further investigation. The presence of a safety signal does not mean that a medicine has caused the reported adverse event. The adverse event could be a symptom of another illness or be caused by another medicine taken by the patient. Therefore, evaluation of safety signals is required to establish whether or not there is a causal relationship between the medicine and the reported adverse event.

Signals are generated from several sources such as spontaneous reports, clinical studies and the scientific literature. One of the most important sources for detecting safety signals is EudraVigilance, European adverse reactions database. The evaluation of safety signals is part of routine pharmacovigilance activities, through which the benefit-risk balance of a medicine is actively monitored and managed.

**Fig no.9**

The European Medicines Agency (EMA) and the national regulatory authorities of EU Member States are continuously monitoring data in the EudraVigilance database to detect the occurrence of new risks, the change of existing risks and to assess whether those risks have an impact on the benefit-risk balance of a medicine. On the national level, the regulatory authorities are detecting signals for the active substances of medicinal products which are authorised in particular Member State. Additionally, at the European level there exists the list of active substances contained in authorised medicines for which a lead Member State has been appointed to monitor data in EudraVigilance, with the aim of validating and confirming the signals.

HALMED is actively and continuously monitoring, analysing, prioritising and evaluating the signals at both described levels.

Member States are evaluating all potential signals through participation in the work of EMA's Pharmacovigilance Risk Assessment Committee (PRAC). Signal management encompasses the analysis, prioritization and assessment of signals, resulting in a PRAC recommendation. These recommendations may relate to any medicine with a valid marketing authorisation in the EU, including nationally and centrally authorised medicines.

In cases where a causal relationship is confirmed or considered likely, the concerned MAHs may be asked by the PRAC to provide further information. PRAC recommendation in principle relates to regulatory action, such as an update of the Summary of product characteristics (SmPC) and the package leaflet (PL). PRAC recommendations for regulatory action concerning centrally authorised medicines are submitted to the Committee for Medicinal Products for Human Use (CHMP) for endorsement. If the signal concerns nationally authorised medicines, PRAC recommendations for regulatory action are submitted to the Coordination Group for Decentralised and Mutual Recognition Procedures - Human (CMDh).

Constitutional objectives of pharmacovigilance program of India

The Pharmacovigilance Programme of India (PvPI) was operationalized in July 2010 by the Ministry of Health & Family Welfare (MoHFW), Government of India (GoI) with a mission to reduce the risks associated with the use of medicines in the Indian population. The AIIMS, New Delhi was established as the National Coordination Centre for PvPI (NCC- PvPI). Later on, the Ministry of Health & Family Welfare (MoHFW), Government of India (GoI) on 15 April 2015, recast this program and shifted the National Coordination Centre from AIIMS, New Delhi to Indian Pharmacopoeia Commission (IPC), Ghaziabad. The Materiovigilance Programme of India (MvPI) to monitor the safety of medical devices and the Haemovigilance Programme of India (HvPI) to monitor the safety of blood & blood-related products are also the integral part of PvPI and their NCCs are located at IPC & National Institute of Biologicals (NIB), Noida.

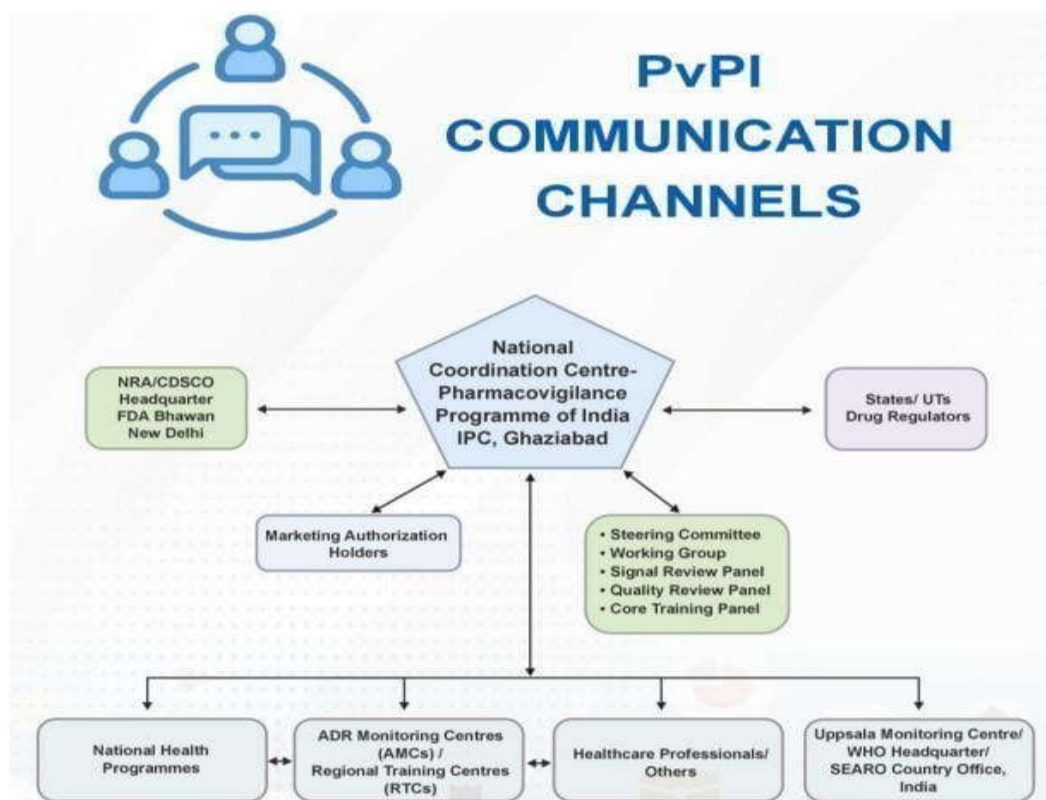


Fig no.10

VISION, MISSION & OBJECTIVES OF PvPI

Vision

To improve patient safety and welfare of the Indian population by monitoring safety of medicines, thereby reducing the risk associated with their use.

Mission

To safeguard the health of the Indian population by ensuring that the benefits of use of medicine outweigh the risks associated with its use.

Important Objectives

To create a nation-wide system for medicines safety reporting and monitoring. To identify and analyze new signals from the reported cases.

To communicate to various stakeholders the safety information on use of medicine so as to prevent/minimize the risk.

To support the National drug regulators in the decision-making process on use of medicine.

List of National Adverse Drug Monitoring Centers (AMCs) and their functions

The functions of National Drug Monitoring Centers :-

The Pharmacovigilance Programme of India (PvPI) has a network of Adverse Drug Monitoring Centers (AMCs) across India. These AMCs are responsible for collecting and following up on adverse drug reaction (ADR) reports from patients. The functions of the AMCs include:

Monitoring ADRs :

AMCs monitor ADRs to ensure that the benefits to medicine outweigh the risk. The institute has been designated as Adverse Drug Reaction (ADR) Monitoring Centre under Pharmacovigilance Programme of India (PvPI) in December 2012, by Indian Pharmacopoeia Commission (IPC) under Ministry of Health and Family Welfare, Government of India.

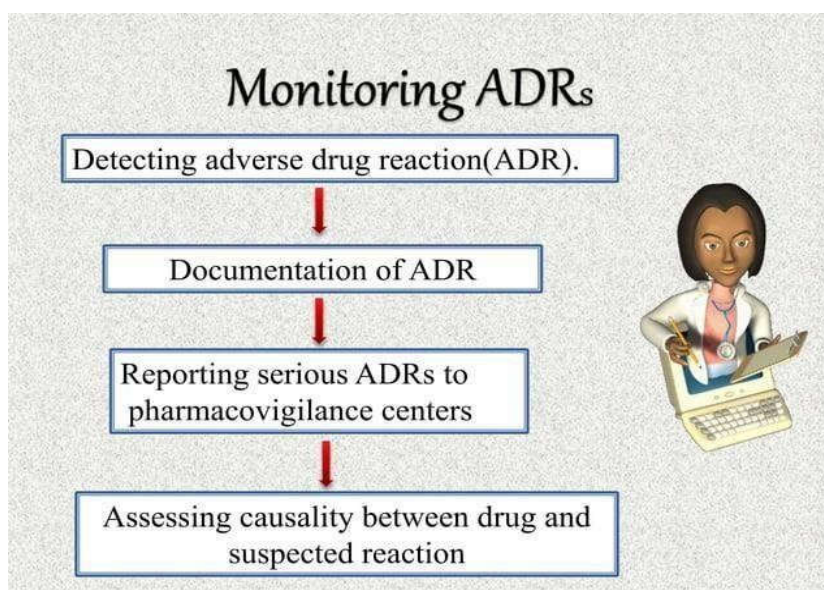


Fig no.11

ADR Monitoring (Pharmacovigilance) Centre (AMC) is located in the Department of Pharmacology and HOD Pharmacology is the Coordinator. PvPI is concerned with reporting of ADR “to ensure the benefits of use of medicine outweigh the risk and so safeguarding the health of Indian Population” i.e. Safe use of medicines. Apart from ADR monitoring of drugs, Haemovigilance (Adverse Events/ Reactions associated with Blood Transfusion & Blood Products Administration) and Biovigilance Programme (Adverse Events/Reactions during

tissue, Organ & Cell Therapy Transplantation) have also been included under PvPI. Reporting of ADR is voluntary, however, it can be considered as ethical and moral duty of every medical professional to ensure the safety of patients while providing treatment, whether by medicines or by other means. Now, it is very convenient for staff members by sparing just five minutes of their valuable time to report adverse drug reactions (including that arise due to blood and bloods products and tissue transplantation) to AMC of SMIMER. The ADRs reported are sent every month to IPC for necessary action (intervention) and further onward submission to WHO.

Creating awareness: AMCs educate healthcare professionals on the importance of reporting ADRs. Some ways to creat awareness:-

Social media

Use to Identify keywords, listen to conversations, and respond to concers. We can also share compaign materials on social media to encourage people to report adverse drug reactions.

Incorporate into curriculum

Include pharmacovigilance coaching in the curriculum of healthcare providers.

Creat awareness in the community

Build relationships with key stakeholders, such as patients and healthcare providers. You can also support local volunteering initiatives.

Use videos

Create videos to explain the history of the organization and the perspectives of pharmacovigilance professionals.

Use comics

Create comics that explore different aspects of the safe use of medicines.

Implement post-market monitoring

Government agencies can implement post-market monitoring mechanisms to improve drug regulation systems.

Generating evidence-based recommendations on the safety of medicines :

Evidence-based information in pharmacovigilance is generated using a variety of methods, including:

Real-world evidence (RWE)

Data collected from real-world clinical settings, such as healthcare databases, registries, claims databases, social media, and patient platforms. RWE can be used to generate pharmacovigilance data through post-marketing surveillance.

Big data

Electronic methods are used to analyze large volumes of information about adverse drug events (ADEs) in spontaneous reporting systems (SRS) databases. Big data methods can identify new associations between drugs, ADEs, and risk factors.

Case reports

Case reports published in journals can be used to generate hypotheses.

Artificial intelligence (AI)

AI-based systems can automatically detect events, integrate data from multiple sources, and optimize AI algorithms. AI can help reduce the workload of manual case processing.

The goal of pharmacovigilance is to reduce harm by helping people use medicines more appropriately.

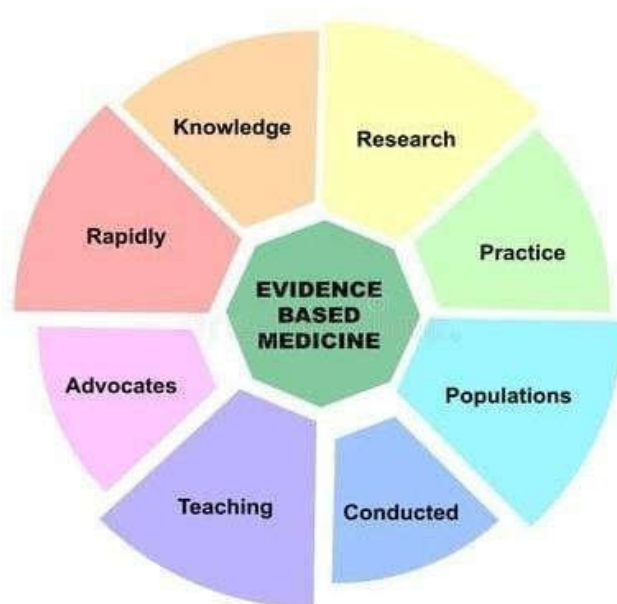


Fig no.12

Supporting the CDSCO in formulating safety-related regulatory decisions for medicines :

Monitoring ADRs: PvPI monitors adverse drug reactions (ADRs) in the Indian population

Generating recommendations: PvPI generates independent, evidence-based recommendations on the safety of medicines.

Communicating findings: PvPI communicates findings with key stakeholders.

Sharing adverse reactions: PvPI shares adverse reactions reported for vaccines with the district immunization officer, state AEFIC committee, and the national AEFIC committee.

Creating a national center of excellence: PvPI works to create a national center of excellence for drug safety monitoring.

Collaborating with international health agencies: PvPI collaborates with other international health agencies.

CDSCO uses the recommendations from PvPI to make regulatory decisions on the safety and efficacy of pharmaceutical products. CDSCO uses evidence-based information to make decisions such as updating the Prescribing Information Leaflet (PIL), issuing drug alerts, and signals.

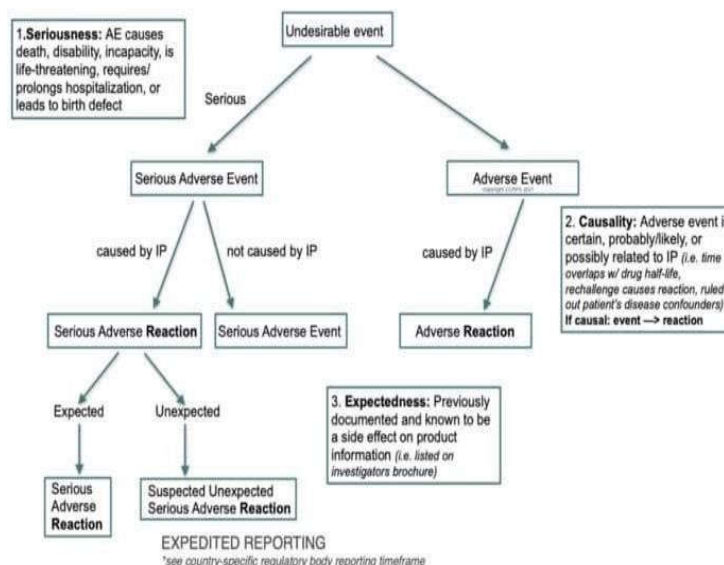


Fig no.13

Communicating findings with key stakeholders :

Effective communication with key stakeholders is essential for ensuring the safety of drugs and vaccines, and protecting public health. Here are some ways to communicate findings with key stakeholders in pharmacovigilance:

Establish clear channels of communication

Define roles and responsibilities, and escalation processes for all parties involved in drug safety management.

Report adverse drug reactions (ADRs) promptly and accurately

This helps detect potential safety issues, identify patterns or trends, and take necessary actions to mitigate risks.

Involve patients

Patients can play a role in pharmacovigilance by reporting directly, participating in patient organizations, or serving as expert patients.

Collaborate with diverse stakeholders

Stakeholders include regulatory authorities, patients, healthcare providers, and the pharmaceutical industry.

Engage media and celebrities

Some suggest that engaging media and celebrities can help disseminate information.

Offer incentives

Some suggest that offering incentives and recognition certificates to doctors and heads of hospitals can increase the number of ADR reports.

List of National Adverse Drug Monitoring Centers

416 Maharashtra TN Medical College & Byl Nair Hospital, Dr. AL Nair Road, Mumbai Central, Mumbai, Maharashtra – 400008 Government (State) TNMC-Mumbai 2012 Pharmacology Dr. Renuka Kulkarni Munshi N/A 417 Maharashtra Seth GS Medical College & KEM Hospital, Acharya Donde Marg, Parel, Maharashtra - 400012 Government KEM- Mumbai RNTCP KEM-Mumbai Before 2011 Pharmacology Dr. Nithya Gogtay (Prof & Head) Dr. Mahesh Belhekar 418 Maharashtra Govt. Medical College, Sangli District, Miraj, Maharashtra – 416410 Government (State) GMC-Miraj 2014 Pharmacology Dr. Shreyas Ramchandra Burute Associate Professor Dr. Nitin Nathuji Puram Assistant Professor 419 Maharashtra Swami Ramanand Teerth Rural Govt Medical College, Ambajogai, District. Beed, Maharashtra – 431517 Government (State) SRTRMC-Beed 2011 Pharmacology Dr Asha Dattatraye Jadhav Dr. Mangal Kishanrao Choure 420 Maharashtra Govt. Medical College & Hospital, Ajni Rd, Nagpur, Maharashtra – 440003 Government (State) GMCH-Nagpur 2012 Pharmacology Dr. S.M Mahakalkar, Professor & Head, Pharmacology Dr. M.V Kalikar, Associate Professor, Pharmacology 421 Maharashtra Mahatma Gandhi Institute Of Medical Sciences, Sevagram, Wardha, Maharashtra – 442102 Non-Government MGIMS-Wardha 2011 Pharmacology Dr. Devesh Gosavi Dr. Leena Chimurkar 422 Maharashtra Indira Gandhi Govt. Medical College, C.A. Road, Nagpur, Maharashtra – 440018 Government (State) IGGMC- Nagpur 2011 Pharmacology Dr. Vandana Avinash Badar Dr Amrita Prakash Singam. Assistant prof dept of pharmacology 423 Maharashtra Dr. Vaishampayan Memorial Govt. Medical College, Opp. District Court, Solapur, Maharashtra – 413003 Government (State) DVMGMC- Solapur 2016 (Associate \Prof. & HOD, Pharmacology) Dr Rupali Jadhav (Asst. Professor)

N/A 424 Maharashtra N.K.P. Salve Institute of Medical Sciences & Lata Mangeshkar Hospital, Digdoh Hills, Hingna Road, Nagpur, Maharashtra – 440019 Non-Government NKPSIMS- Nagpur 2015 Pharmacology Dr. R. A. Siddiqui (Asso. Prof, Pharmacology Dept) Dr Shadma Quazi 425 Maharashtra Armed Forces Medical College, Opp. Race Course, Solapur Road, Pune Cantonment, Pune, Maharashtra – 411040 Government (Central) AFMC-Pune 2014 Pharmacology Maj Dr. Bhupendra Solanke Dr Durgaprasad Boddepalli. 426 Maharashtra BJ Medical College & Sassoon General Hospital, Jai Prakash Narayan Road, Near Pune Railway Station, Pune, Maharashtra – 41101 Government BJGMC-Pune ARTBJMC-Pune 2011 Pharmacology Dr. Pardesi Milindkumar Laxman Rao (Coordinator changed) Dr. Nitin Chintaman Gawari htra Grant Medical College & Sir JJ Group of Hospital, JJ Marg, Off Jijabhoy Road, Byculla, Mumbai, Maharashtra – 400008 Government GMCJJ-Mumbai ARTGMCJJ-Mumbai 2011 Head of the Department of Pharmacology. Dr. R.S. Gambre N/A 428 Maharashtra Lokmanya Tilak Municipal Medical College & General Hospital, Dr. Babasaheb Ambedkar Road, Sion, Maharashtra – 400022 Government LTMMCGH-Mumbai 2011 Pharmacology Dr. Sudhir R. Pawar Dr. Neha Kadhe

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