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REVIEW ON CONCEPT OF PHARMACOVIGILANCE

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ABSTRACT

A crucial step in the drug development process is pharmacovigilance, which assists in identifying the adverse event profile of any medication. Years after the WHO's International Drug Monitoring Program was launched, the Indian government launched the Pharmacovigilance Programme of India (PvPI) in 2010. PvPI's primary purpose is to monitor the Effectively manage adverse drug reactions (ADR) by establishing a number of Adverse Drug Reaction Monitoring Centers (AMC) throughout India and hiring staff with the necessary skills. PvPI has been crucial in raising healthcare professionals' (HCPs) knowledge of the significance and procedure for reporting Adverse Drug Reactions (ADRs), which has resulted in a multiplication of ADR reporting. The Pharmacovigilance Program of India (PvPI) is a key player in compiling information about drug safety and entering it into the WHO database. PvPI satisfies the WHO's minimal standards for any operational national pharmacovigilance program. Under PvPI, the national coordinating center is the Indian Pharmacopoeia Commission (IPC).When a medicine is "noxious, unintended, and occurs at doses normally used in man," an adverse drug reaction (ADR) results.

Key words : Pharmacovigilance, Adverse Drug Reaction (ADR), Pharmacovigilance Programme of India (PvPI)

INTRODUCTION

According to WHO Pharmacovigilance is " experimentation and activities concerned with the perception ,assesment , grasping and prohibition of drug related toxic /side effect/ adverse effect or other problems" and it is useful to make sure that patient received safe drug[1] .Data processing speed increases with the number of adverse drug reactions (ADRs). Risk management and process definition issues in the context of clinical trials and post-marketing pharmacovigilance are complex. However, given the number of ongoing clinical trials and clinical research activities in India and the increasing levels of clinical trials and pharmacoepidemiological research, there is an urgent need to understand and utilize pharmacovigilance.

When thalidomide was first developed in 1954 and made available to the public in 1956, it was recommended as a safe treatment for morning sickness and nausea. The company removed thalidomide from the market on November 25, 1961. It was estimated that 6,000 to 12,000 newborn babies were born with serious birth defects because their mothers used thalidomide.[2]

As a result of the thalidomide tragedy that had occurred in Europe, lawmakers passed the Drug Efficacy Amendments (also known as the Kefauver-Harris Amendments) in 1962, which is generally acknowledged to have marked the beginning of PV as a distinct, definable activity in the United

States.4 On the other hand, the statute was significantly shaped by prior history. The United States of Food and Drug Administration (FDA) began aggressively seeking details on a developing safety concern related to the use of chloramphenicol as early as 1952. [3]

Concept of pharmacovigilance:

Pharmacovigilance meaning

Pharmakon (Greek) = Medicinal substance

Vigilia(Latin) = To keep watch

DEFINITION

According to WHO Pharmacovigilance is " experimentation and activities concerned with the perception ,assesment , grasping and prohibition of drug related toxic /side effect/ adverse effect or other problems" and it is useful to make sure that patient received safe drug [4]

HISTORY OF PHARMACOVIGILANCE INDIA

Pharmacovigilance in India began in 1986 with the establishment of adverse drug reaction (ADR) surveillance comprising 12 regional centres, each under its own jurisdiction. India received a $50 million deal. But a major change came a decade later, in 1997, when India joined the Adverse Drug Reactions Surveillance Program of the World Health Organization, headquartered in Uppsala, Sweden. Following this failed attempt, the National Pharmacovigilance Program of India, funded by the World Bank and supported by the World Health Organization, was launched on 1 January 2005. (Nagaandla and Garlapati, 2015)

The Central Drug Control Center (CDSCO) in New Delhi hosts the National Advisory Committee on Pharmacovigilance and manages the National Pharmacovigilance Program established in January 2005. There are two regional centres: the North East Regional Center and the South West Regional Centre. Department of Clinical Pharmacology, Seth J.S. Medical School. KEM Hospital, Mumbai.

Data from across the country will be collected from the regional center at the AIIMS Institute of Clinical Medicine in New Delhi and sent to the committee and the Swedish Monitoring Center in Uppsala. There would be two regional centers reporting to the New Delhi center and three to the Mumbai center. A number of peripheral centers would report to each regional canter in turn. There are 26 peripheral canters at the moment. There are three main goals for the program.[5].

Table No. 1 : The sequential developments of Pharmacovigilance with special reference to India[6].

Sr.No.	Year	Development
1	1747	James Lind conducted the earliest documented clinical research demonstrating the effectiveness of lemon juice in reducing scurvy.
2	1937	Over a hundred children have died as a result of sulfanilamide poisoning.
3	1950	Aplastic anemia linked to poisoning from chloramphenicol
4	1961	Global catastrophe brought on by thalidomide toxicity
5	1963	The 16th World Health Congress acknowledges the importance of acting quickly to address adverse drug reactions (ADRs).
6	1968	A WHO study aimed at global drug surveillance Pilot scale
7	1996	India launched a clinical trial at the global standard level.
8	1997	The WHO Adverse Drug Monitoring Program is linked to India.
9	1998	Pharmacovigilance's beginnings in India
10	2002	India's 67th National Pharmacovigilance Center has been formed.
11	2004-05	National Pharmacovigilance Programme introduced in India
12	2005	In India, systematic clinical trials are completed
13	2009-10	The Pharmacovigilance Program Initiated (PvPI)

NEED OF PHARMACOVIGILANCE

Medication therapy is often considered a complex process that takes a long time to complete. Once on the market, the drug is free for public consumption, thus leaving a safe and reliable scientific environment for drug testing. Most medications have only been tried on a small number of carefully chosen people for short-term safety and efficacy at this stage. Therefore, the need for pharmacovigilance arises, which requires the creation of special procedures to control such risks and ensure early detection of side effects or grouping patients with special effects.. Furthermore, it is crucial to evaluate novel and medically developing treatments for their efficacy and safety in real-world situations. What happens after work? Additionally, additional data are often needed to understand the safety and effectiveness of long-term use with other medications in special populations such as children, pregnant women, boys, and adults. Later in the medicine's release years, a number of side events, drug interactions, and risk factors were reported.[7-8]

Aim of Pharmacovigilance

For human medications, the primary goals of pharmacovigilance have been established (Stephens, 2000) , and these goals are easily transferable to veterinary medications:

- Determining and quantifying adverse medication reactions that were previously unknown.
- Determining patient subgroups that are particularly vulnerable to adverse medication reactions, such as those based on species, breed, age, gender, physiological state, or underlying medical condition.

- Ongoing assessment of a product's safety in each species for which it is approved, to make sure that the advantages outweigh the dangers. Monitoring efforts ought to be expanded to incorporate new species and signals.
- Assess how antibodies vary between products within and between animals in the same treatment unit
- Identify inappropriate medication and administration; in relation to the latter, public or farmer administration may be necessary. To be supervised.
- Additional research on the microbiological, pharmacological, or toxicological characteristics of a medication or product in an effort to comprehend the causes driving adverse drug responses, when feasible.
- The identification of drug-drug combinations. This is especially crucial for newly developed medications that are provided alongside existing ones or even other newly developed medications.
- To provide information regarding drug interactions and side effects to veterinarians and other healthcare providers, veterinarians, farmers and other animal owners.
- Side effects on the environment and surrounding organisms caused by veterinary medications.
- The overuse of veterinary medications in animal-derived foods, including meat, milk, and honey, beyond allowed residue limits.
- Rules and laws pertaining to the necessity of pharmacovigilance,[9][10].

Objectives of Pharmacovigilance

- To set up a nationwide mechanism for reporting patient safeness.
- Identify and investigate adverse reactions (ADRs) in recorded data.
- evaluate marketed medications' benefit-risk ratios
- produce evidence-based safety medicine information
- Help organizations make decisions regarding drug use
- disseminate safety information about medication use to different stakeholders in order to reduce the risk
- To become one of the leading national hubs for pharmacovigilance initiatives.
- To work together with national hubs for data management and information exchange
- To encourage public communication that is effective.
- To encourage the prudent and secure administration of medications. [11]

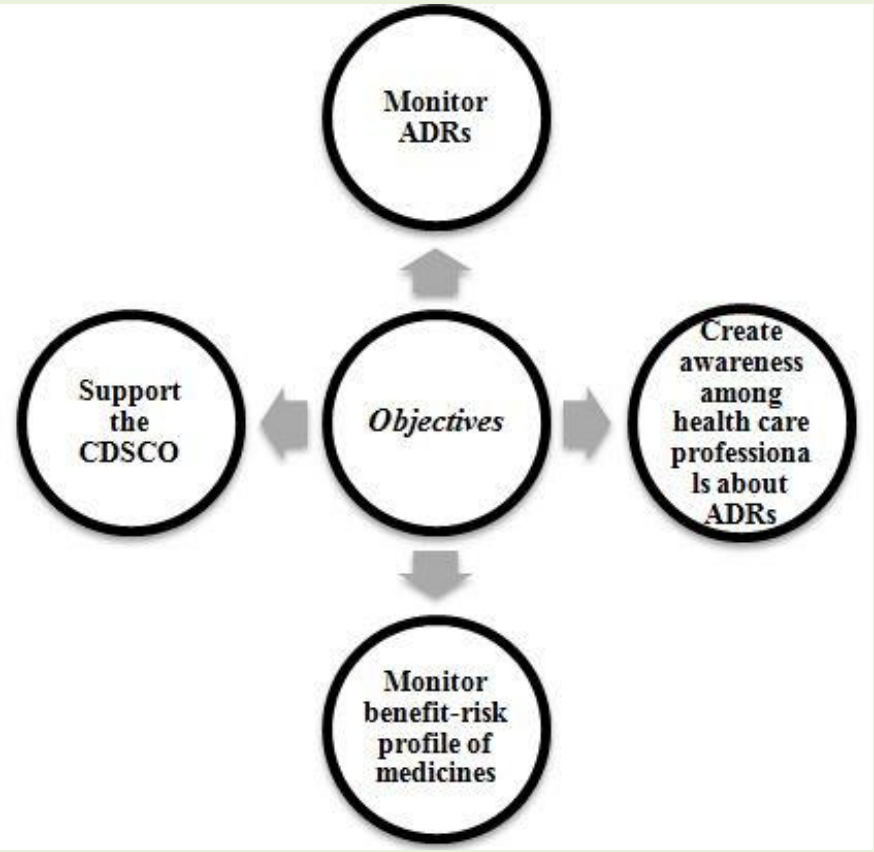

Fig 1: objectives of pharmacovigilance

Types of Pharmacovigilance

- Passive surveillances
- Active surveillance
- Comparative observational studies
- Clinical studies

1)Passive surveillance

a) Spontaneous reporting
b) Stimulated reporting
c) Intensified reporting
d) Targeted spontaneous reporting

a) Spontaneous reporting

- A functional ADR system that monitors the security of every medication.
- An Reports to the Pharmacovigilance Center are voluntarily submitted by patients, pharmaceutical companies, and healthcare providers.
- Suspected ADRs serve as the basis for reporting systems.
- A Either a local or central database is used to collect and store data.
- The reporting form comprises details on the patient, the reporter, and the suspected product.
- It also provides an explanation and details of a claimed reaction.

- This data is predicated on potential adverse drug reactions.
- There is no systematic collection of cases.

b) Stimulated reporting

- A technique to support and encourage health experts to report on new items or for a limited time.
- Techniques for systematic AE reporting on-line and encouraging AE reporting .

Drawback

- Statistics are frequently lacking.
- Unhelpful for calculating an accurate incidence rate

c) Intensified reporting

- This is an upgrade to an unprompted reporting software.
- It makes an effort to enhance early post-marketing ADR reporting for certain specific medications.
- Usually, the procedure is adhered to for new drugs, biological drugs, and drugs requiring additional investigation.
- For instance, antiretroviral medications given via an alternative program

b) Targeted spontaneous reporting

- This method is employed to learn more about the population-based adverse drug reaction profile of a medication.
- To determine how common an adverse drug reaction (ADR) is in a given group.
- Keeping an eye on renal toxicities linked to tenofovir-based antiretroviral treatment regimens, for example

2) Active surveillance

- Unlike passive observation, active surveillance is a constant, pre-planned technique to try and pinpoint the exact amount of unwanted incidents. Generally speaking, in contrast to a passive reporting system, an A system that actively monitors adverse event reports has a higher probability of collecting substantial information on individual complaints.

a) Sentinel sites

Active monitoring can be done by reviewing medical records or talking to patients and doctors in specific areas of the referral site to ensure that information is expanded and improved. A reliable number of adverse events are collected from these sites.

The chosen sites may provide patient subgroup data unavailable through the passive spontaneous reporting method.

b) Cohort study

To track the disease's development, the population at risk is regularly observed. During each patient's follow-up period, exposure status data is accessible. The drug may be given to a patient during follow-up at one time but not at another.

In the many cohort studies on drug exposure, participants are selected according to their past medication use and are followed over time. When understanding adverse event incidence rates in addition to relative risks is necessary, cohort studies might be helpful.

They could not include all the pertinent data required for a particular research study, such as validated diagnostic data or laboratory results, since they are made for administrative or billing purposes. Given that test results and diagnoses can be produced and verified using patient medical data, one should be cognizant of the privacy and Criteria for privacy that are relevant to this data.

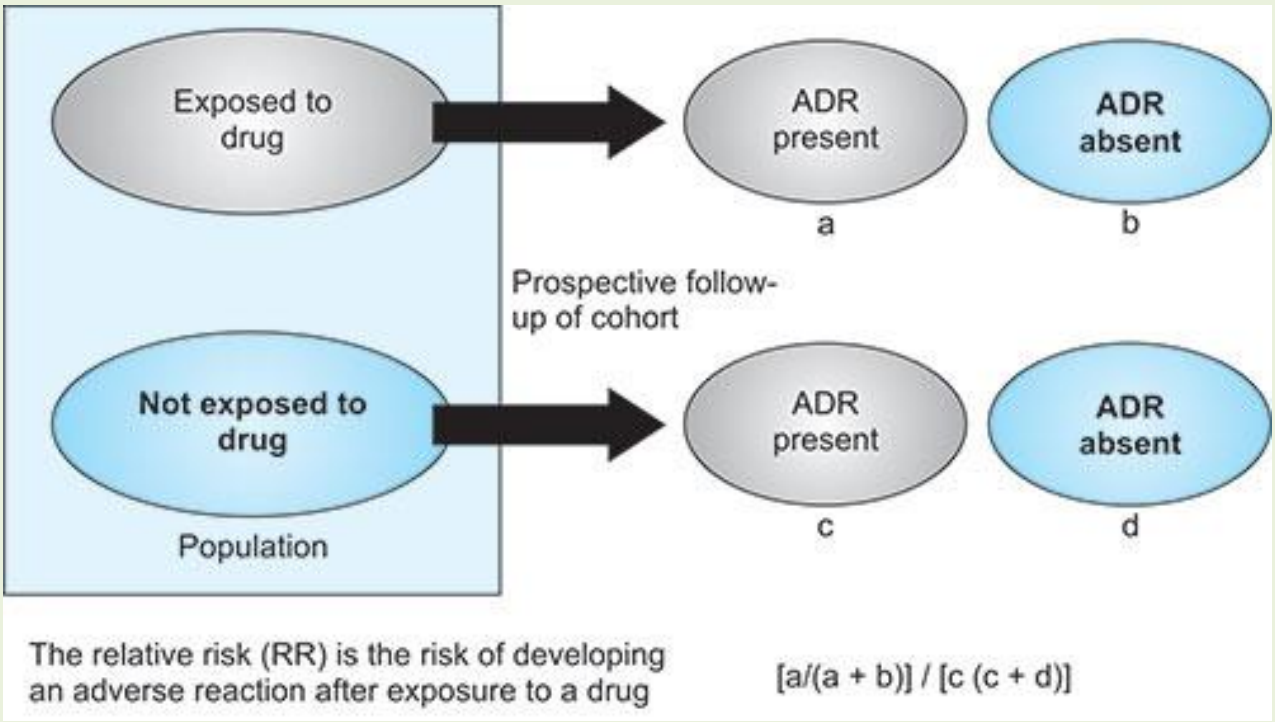

Fig .2: Cohort study

c) Registries

- A registry is containing list of patients having similar symptoms . For example: medical records or pregnancy records.
- Vary from one another based on the patient's type
- A common questionnaire can be used to gather information.

e) Cross -sectional study

Over a predetermined period of time, a cross-sectional study gathers information on patients' residents regardless of exposure or disease status.

f) **Specific clinical research**

Pharmacodynamic and pharmacokinetic investigations may occasionally be required to ascertain whether a certain dose recommendation will raise the risk of unfavorable patient outcomes. Furthermore, based on the drug's pharmacological characteristics and expected use in clinical practise, it could be beneficial to carry out Particular research to evaluate potential interactions between drugs and foods.

The drawback of this strategy could be an overly short outcome measure, which could detract from the trial's overall quality and the significance of its conclusions. Larger, more straightforward experiments need comparable resources.

g) Case control study

Finding illness cases (or occurrences) is the goal of a case-control study. Next, carefully selected individuals with the disease or those in whom the relevant event has not occurred are used as controls or as individuals from the population that served as the case's source**.**

It is important to choose the controls so that the exposure prevalence of the source population may be contrasted with the control group's. The prevalence of the two groups was compared by the prevalence difference, which is an assessment of the relative prevalence of the disease between the two groups.

3) Comparative observational study

In a **cross-sectional study:** data from the patient population can be linked to a particular point in time, independent of exposure or illness state.

A **case control study** uses information acquired specifically for the study or an existing database to identify cases or patients who have had adverse outcomes.

4) Cohort event monitoring

- A cohort is a group of people with a common characteristic, such using drugs throughout a particular time period.
- This study is an observational prospective cohort analysis of unfavorable outcomes associated with one or more drugs.
- The trial was planned before the medication's therapy began.
- Since they started getting therapy, every patient has had their adverse occurrences tracked and recorded.
- ADR tracking for antiretroviral medications, for instance[12]

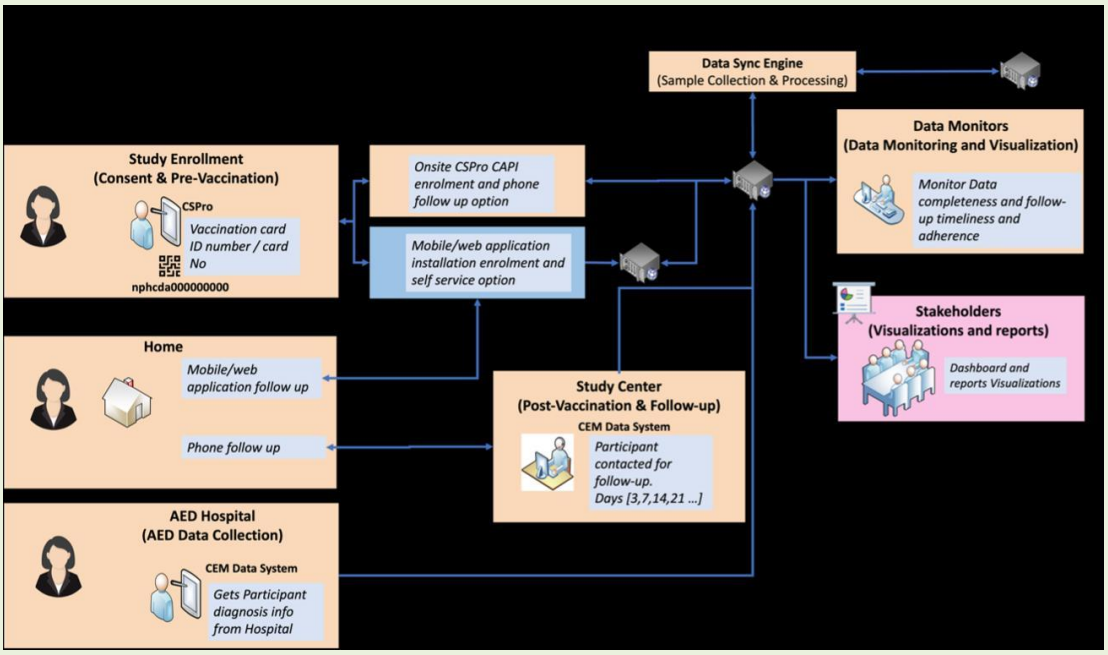

Fig 3 : Cohort event monitoring

Role of Pharmacovigilance in different sectors :

Pharmacovigilance in regulation of medicine:

Strong regulatory frameworks serve as the cornerstone for both public trust in medicines and a national ethos of drug safety. The jurisdiction of drug regulating bodies must expand for it to be successful.

covers a wider range of issues related to pharmaceutical safety than only the approval of new drugs, such as:

• clinical studies;

• the security of biological, supportive and indigenous medicines;

• the creation of channels of conveying amongst all stakeholders with an attentiveness in medication harmlessness guaranteeing their ability to operate effectively and morally, especially during emergencies.

Drug regulatory agencies and pharmaceutical surveillance programs need to work together to accomplish their respective goals. Pharmacovigilance programs must, on the one hand,

Keep close ties with the drug regulatory authorities to make sure they are informed of safety concerns in routine clinical practice, regardless of whether these concerns are related to upcoming regulatory actions or concerns that become public. Conversely, authorities must comprehend the specific and essential function that pharmacovigilance fulfills in guaranteeing the continuous safety of pharmaceuticals.

Pharmacovigilance in clinical practice:

A fundamental component of clinical practice ought to be the safety monitoring of commonly used medications. The extent of clinicians' knowledge on the principle.They contend that the practise of pharmacovigilance has a significant influence on the standard of healthcare. Effective patient care is improved through clinical experience with medicine safety being linked to research and health policy, information sharing between national pharmacovigilance centers, coordination of this information sharing, and Physicians need to receive education and training on medication safety. Through consistent information sharing, national pharmacovigilance programs are in a prime position to pinpoint knowledge gaps about medication-induced illnesses.

Pharmacovigilance in public health programs for disease control :

The oversight of medication safety in nations lacking regulatory frameworks or safety monitoring systems, as well as in isolated regions with inadequate or non-existent healthcare facilities, Infrastructure and monitoring have been noted as areas of concern. The issues are most noticeable when medications are used in particular communities, such as when treating tropical illnesses like malaria, Leishmaniasis and bilharzia, as well as for the management of TB and HIV/AIDS. In certain contexts, numerous disease control programs that involve giving medications to big populations Are being administered to the same population without any consideration for the potential interactions between these different medications.

Pharmacovigilance ought to be a top priority in any nation that has a public health disease control initiative [13].

Component of Pharmacovigilance

For pharmacovigilance operational models to become proactive, resource-efficient, and business-aligned, they must concentrate on four essential elements:

1) **Core capabilities:**

Pharmacovigilance provides pharmaceutical companies with four main capabilities**:**

- Management of adverse event cases, including accelerated reporting
- Reporting in aggregate;
- Signal Processing; and
- Control of Risks.

2) **Strategy:**

Each product's benefit-risk characteristics need to be considered in business planning. By creating a robust benefit-risk profile and enhancing the identification of patients who are at-risk, pharmacovigilance, when well executed, can generate competitive advantage.

3) **Global network:**
To preserve visibility and consistency while enabling local responsiveness, pharmacovigilance (PV) must attain worldwide coverage and a network of centralized and local capabilities as well as a variety of regulatory frameworks tailored to various markets.

4) **Governance :**
Clear governance is necessary for the effective escalation and settlement of issues. A closely connected, closed loop procedure. A crisis management procedure used by the entire organization can reduce safety hazards while upholding compliance.

Other components of Pharmacovigilance:

- Pharmacovigilance officer in charge (PvOI)
- Safety system support
- Global safety reporting team
- Medical writing team
- SOP's Quality standards and training signal and risk analysis
- Risk management
- Data collection
- Adverse event case management [14]

Pharmacovigilance programme of India (PvPI)

When the 12-center Adverse Drug Reaction Monitoring System was established in 1986, there was no specific decision or action regarding pharmacovigilance. (Camacho, 2016) In 1997, India joined the Adverse Drug Reactions Surveillance Program of the World Health Organization in Uppsala, Sweden. The level of cooperation required to support pharmacovigilance activities is insufficient.

Accordingly, the Government of India launched the Pharmacovigilance Program in India (PvPI) on July 14, 2010. The All India Medical Institute (AIMS), New Delhi, has chosen the National Coordination Center (NCC) for PvPI certification to protect public health. Product safety. In 2010, approximately adverse medication reaction monitoring centers were established

On April 15, 2011, NCC was shifted from AIIMS, New Delhi to IPC and Ghaziabad to ensure smooth and efficient operation of the programme. AMCs, or adverse drug reaction monitoring centers, were permitted for use in a limited number of qualified medical colleges, hospitals, and clinics. These AMCs collect, review, and submit Individual Security Risk Reports (ICSRs) to the appropriate regulatory agencies. As of January 2017, 250 AMCs (public and non-governmental) have been established under PvPI. Twenty anti-retroviral therapy (ART) cases and seventeen Additionally, updated National Tuberculosis Program (RNTCP) centers were set up to facilitate the reporting of spontaneous adverse medication reactions. An approved individual is the technical associate from Banaras Hindu University's Medical Sciences department who collects ICSRs, follows up on them, and enters them into the Vigi-Flow software's online database.

All community health centres (CHCs) and primary health care centers (PHCs) provide reports to the regional center regarding adverse drug reactions. It was believed that the Natural medicines don't cause bad medication reactions and are safe. However, the foundational text of Ayurveda, "Charka Samheta," shows that improper compounding and dispensing of herbal medications can also result in adverse drug reactions (ADR). Therefore, in accordance with WHO criteria, it was crucial to

provide ADR data for AYUSH medications in order to submit PV for Ayurveda, Siddha, and Unani (ASU)

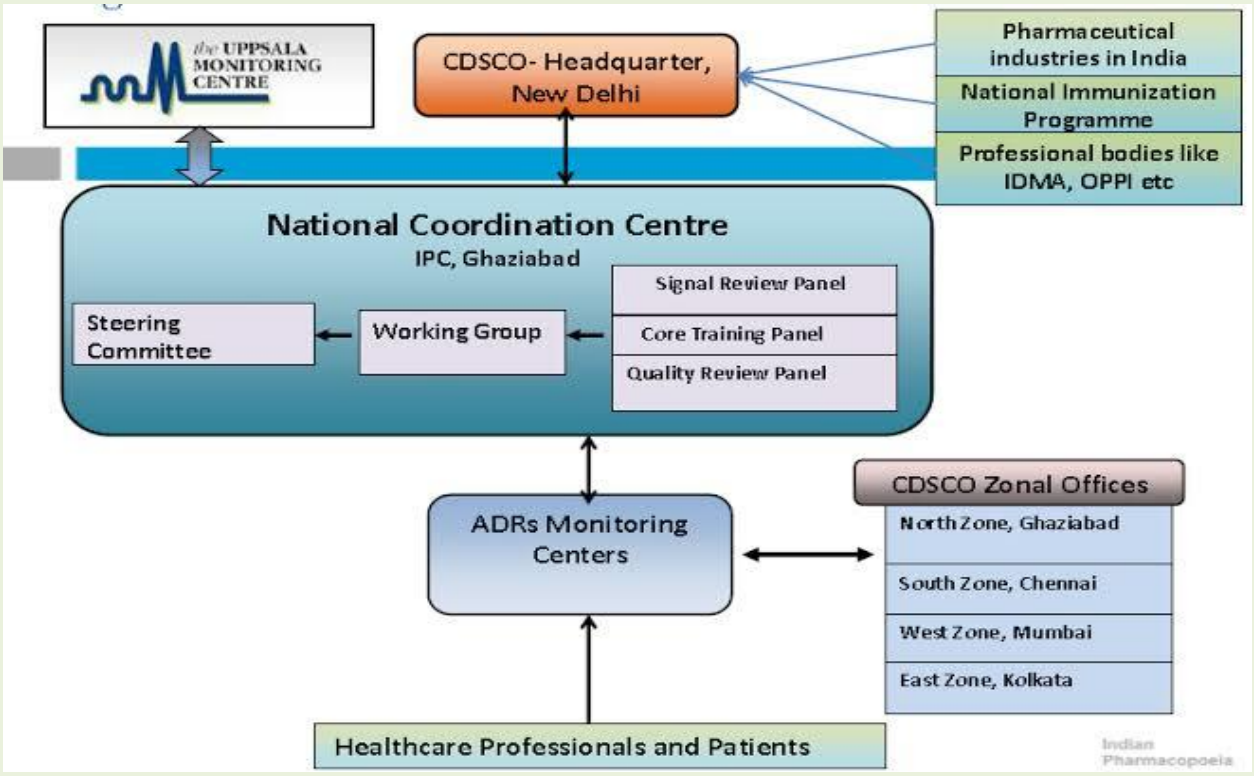

Fig .4 : Pharmacovigilance Programme of India

Implementation of Pharmacovigilance Program in India (PvPI):

The IPC presumably perceived the need for local hospital-based centers to be developed around the nation in order to improve patient safety.

It was crucial to keep an eye out for any updates on the drugs' safety profile in order to learn anything new. Adverse effects that were both previously identified and unknown.

Considering India's size (population more than 1.2 billion) and the disparity in ethnicity, disease patterns, healthcare systems used and sanitation of people, it must establish a system and conduct good pharmacovigilance and drug safety review.

short-term goals :

- Initiate enrollment in the program for all medical institutes accredited by MCI, catering to the India's northeast, south, east, and west**.**
- To create and execute an Indian system for pharmacovigilance.
- To require medical practitioners to document any adverse reactions to medications, vaccinations, patient treatment equipment, and biological products.
- To gather data and conduct case studies

Lengthy-term goals

- The goal is to make the pharmacovigilance program available to all Indian public, private, and government health program centers..

- The objectives are to establish and execute an electronic reporting system, often known as e-reporting;
- mandate healthcare practitioners to report adverse drug reactions (ADRs); and
- cultivate a reporting culture within the healthcare industry.

Objectives of Pharmacovigilance in India

Track the side effects in the Population of India

To set up a countrywide mechanism for reporting patient harmlessness

identify and investigate the novel signal Adverse drug reaction from the documented cases.

Benefit-risk evaluation of prescription drugs.

To produce information about medication safety that is supported by evidence.

Assisting regulatory bodies in making drug regulatory decisions

Disseminate safety information about medication use to multiple stakeholders in such a way to reduce risk[15].

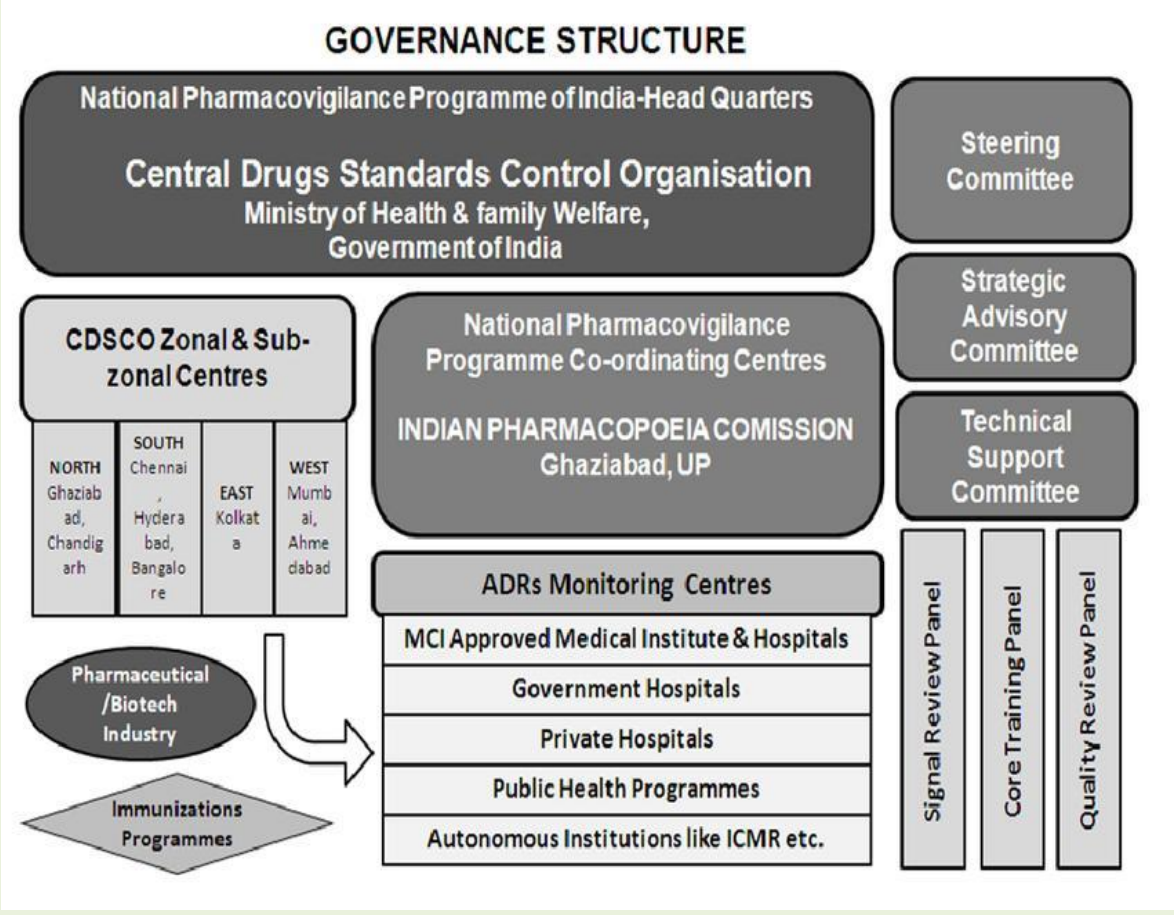

Fig 5: Governance structure

Adverse Drug Reactions (ADR)

The term adverse drug reaction (ADR) is often used to describe drug reactions that are "toxic, unexpected, and occur at doses normally used in humans." This definition is taken from the

Type of Reaction	Property	Eg.
A-Augmented	Related to dose Usual Concerned with known pharmacological effect Expected	Propofol-induced hypotension
B-Bizarre	Not dose related Unusual Uncertain Not concerned with known pharmacological action of drug	Anaphylaxis Overheating that is malignant Apnoea with suxamethonium

1972 World Health Organization (WHO) World Drug Survey and is still widely used today. Today, there are two broad classifications for harmful drugs. The first classification is called type A or fixed (predictable and dose-related) and type B or single (undeterminable and dose negligible)[16].

Table No. 2 : Classification of Adverse Drug Reactions [17]

C-Chronic	Related to dose Related to duration Unusual Concerning the total dosage	Infusion syndrome with propofol
D-Delayed	Related to duration Frequently dose-related Unusual	Nephrotoxicity from fluoride
E- End of use	Occurs during drug discontinuation Unusual	After stopping the clonidine injection, rebound hypertension
F-Failure	Related to dose Unusual Maybe brought on by medication interactions	Oral contraceptive pill failure when using sugammadex

Example of ADR:

Peptic ulcer with Non steroidal anti inflammatory drug :

The most commonly used medications, especially for the elderly, are nonsteroidal anti-inflammatory drugs (NSAIDs).For more than 75% of any given year, about 40% of people over 65 receive at least one NSAID.NSAIDs have a number of negative side effects, the most significant of which being their potential to cause peptic ulcers in terms of public health . NSAIDs are to blame for 15–35% of all problems resulting from peptic ulcers. NSAIDs are to blame for 3300 senior deaths and 41 000 hospital admissions in the US each year . The similar numbers in the UK are 2000 deaths and 12,000 hospital admissions annually.

In general, 1 in 1200 persons who use NSAIDs for two months or more die from them . Epidemiological studies are very useful in determining risk factors such as advanced age, intolerance history, ulcer or gastrointestinal bleeding . In addition, the numerous NSAIDs available on the market have varying risks of peptic ulcers: While ibuprofen has the lowest risk and azapropazone has a risk that is 9.2 times higher than ibuprofen's, the most often used NSAIDs, including naproxen, have an intermediate risk.

Diclofenac NSAID's capacity to prevent prostaglandin formation is closely correlated with its ulcerogenic potential, and stomach acid exacerbates this effect. By producing leukotrienes, cytokines, proteases, and oxygen-free radicals, neutrophils may potentially contribute to mucosal damage.NSAID-Mediated damage to the stomach mucosa has been reduced using a variety of maneuvers. Proton pump inhibitors and misoprostol co-prescription lowers the incidence of stomach ulcers with NSAIDs, and this is preferable to H2-receptor antagonist use.The discovery of two cyclooxygenase isoforms in which COX-2 has inhibitory effects led to the creation of selective COX-2 inhibitors, including celecoxib and rofecoxib. These new compounds may reduce the risk of peptic ulcers compared to non-selective inhibitors. However, this clinical benefit is offset by the use of low-dose aspirin to prevent cardiovascular disease and by directing high-risk patients (with a history of ulcers) to COX-2 inhibitors. COX-2 inhibitors may also have specific clinical benefits. It has its own safety concerns, such as a lack of antiplatelet effect leading to a higher risk of thrombotic heart disease, potential for allergic reactions, and adverse effects on the kidneys compared to non-selective inhibitors. It is doubtful that the discovery of COX-3 isoforms will eliminate the need for antibiotics and anti-inflammatory drugs, but it may contribute to the development of new analgesic drugs. It is crucial to look for new ways to increase the safety of NSAIDs because of their continuous widespread usage and the possibility for such severe side effects.[18]

Table No 3: (PvPI) has the following list of ADR Monitoring Center: [19]

Sr.No.	Adress	Coordinators	Email Adress
Center for National Coordination D[NCC]			
1	All India Institute of Medical Sciences, New Delhi, Department of Pharmacology	Dr.Y.K. Gupta National coordinator	pvpi.ncc@gmail.com
Monitoring Center for ADRs [AMC]			
1	Government Medical College, Bakshi Nagar, Jammu, Department of Pharmacology, Therapeutics, and Toxicology	Dr.Vishal Tandon	dr_vishaltandon@yahoo.com

2	PGIMER's Department of Pharmacology in Chandigarh	Dr. Bikash Medhi	drbikashus@yahoo.com
3	R.G. Kar Medical College's Department of Pharmacology in Kolkata	Dr. Anjan Adhikari	adr.rjk.pharma@gmail.com
4	Lady Hardinge Medical College's Department of Pharmacology, New Delhi	Dr. H. S.Rehan	harmeetrehan@hotmail.com
5	The Department of Clinical Pharmacology at Seth GS Medical College and KEM Hospital, Parel, Mumbai along	Dr. U rmila Thatte	pvpiitakem@gmail.com
6	Chittaranjan Avenue, Kolkata; Department of Clinical and Experimental Pharmacology, School of Tropical Medicine	Dr. Santanu Tripathi	stm.pvpi@gmail.com
7	Pharmacology Department, JIPMER, Pondicherry	Dr. C Adithan	adithan@yahoo.com
8	Clinical Pharmacy Department, JSS Medical College Hospital, Bangalore	Dr. Parthasarathi G	partha18@gmail.com
9	Department Of Pharmacology,Medical College,Guwahati,Assam	Dr.Mangala Lahkar	dr_mlahkar@rediffmail.com
10	The Mdrass Medical College Institute of Pharmacology in Chennai	Dr. R. Nandini	Pvpi.chennai@gmail.com
11	SAIMS Medical College Indore-Ujjain, Department of Pharmacology	Dr .Chhaya Goyal	chhyagl@gmail.com
12	The pharmacy department at GSVM Medical College in Swaroop Nagar, Kanpur, Uttar Pradesh	Dr. SP. Singh	singhdrsp@gmail.com
13	Pandit Bhagwat Dayal Sharma, Department of Pharmacology, Post Graduate Institute of Medical Sciences, Rohtak, Haryana	Dr. MC Gupta	dr_mcgupta@yahoo.co.in
14	Dayanand Medical College and Hospital's pharmacy department is located in Ludhiana, Punjab.	Dr. Sandeep Kaushal	skaushal1@yahoo.co.in
15	Sher-i-Kashmir, Srinagar, J&K / Department of Clinical Pharmacology	Dr. ZA. Wafai	drzawafai@gmail.com
16	Dehradun, Uttarakhand's Himalayan Institute of Medical Sciences	Dr. DC Dhasmana	dhasmanadc@gmail.com
17	Santosh Nagar, Ghaziabad, Santosh Medical University, Department of Pharmacology	Dr.VC Chopra	vipen.chopra@gmail.com
18	SMS Medical College, Jaipur, Department of Pharmacology	Dr. Mukul Mathur	Mathur_mukul@rediffmail.com,
19	Christian Medical College Vellore, Tamil Nadu, Department of Clinical Pharmacology	Dr. Sujith Chandy	sjchandy@gmail.com

CONCLUSION:

Pharmacovigilance is still an active field to study and clinical practice. It still plays a vital part in addressing the issue raised by the constantly evolving spectrum and strength of medications, the unpredictability of vitamin hazards . Especially when unknown dangers and negative effects occur in the past, it is important to record them, analyze them and convey their importance to the readers to understand the words. The type of pharmacovigilance should be able to identify patients at risk from drug use. It is impossible to totally eradicate adverse medication reactions, even with the most advanced pharmacovigilance systems in place. The healthcare professional's responsibility is to reduce the likelihood of adverse drug reactions by taking preventative measures. Information from medication manufacturers, published primary

literature, and national and international reporting bodies about adverse drug reactions (ADRs) makes prevention feasible.

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