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Concept of Pharmacovigilance and Pharmacovigilance Program in India

Raut Tejaswini Sanjay[1], Wakchaure Tanaya P.[2]

UG Student[1], Guide[2]
Vidya Niketan Institue Of Pharmacy & Research Centre Bota

ABSTRACT:

Disease prevention and treatment have evolved as a result of medications and vaccines. Considering their potential advantages, pharmaceuticals frequently cause undesired and/or unexpected adverse effects. The research and practices involved in identifying, evaluating, comprehending, and preventing side effects or any other issue regarding medications or vaccines are known as pharmacovigilance.

Before being approved for use, all medications and vaccines go through extensive clinical trials to ensure their safety and effectiveness. However, the clinical trial procedure involves investigating the products in a select group of participants that have been selected for only a short period of time. Only after using these drugs for a long time and by a diverse group of people, including those who have other concurrent medical conditions, may some adverse effects become noticeable.

The Government of India's main drug safety monitoring program, the Pharmacovigilance program of India, gathers, compiles, and evaluates problems linked to drugs and forwards recommendations to CDSCO for the implementation of suitable regulatory measures.

One of the primary causes of morbidity and mortality in the globe is adverse drug reactions, or ADRs. ADRs have a negative impact on the healthcare system by raising therapeutic costs and lengthening hospital stays. The expense of managing adverse effects in the general public is quite significant and underappreciated in developing nations. Therefore, using a pharmacovigilance system to assess the safety of medications is essential.

Introduction:

Pharmacovigilance:

The pharmaceutical science that deals with the "collection, detection, assessment, monitoring, and prevention" of adverse outcomes with pharmaceutical products is called pharmacovigilance, or drug safety. Pharmakon, which means drug in Greek, and vigilare, which means to keep watch in Latin, are the roots of the phrase "pharmacovigilance." Pharmacovigilance thus places an intense focus on adverse drug reactions (ADR). Even without having of an adverse event, medication errors that can lead to an adverse drug reaction, such as overdosing, drug misuse and abuse, and drug exposure during pregnancy and lactation, are of interest.

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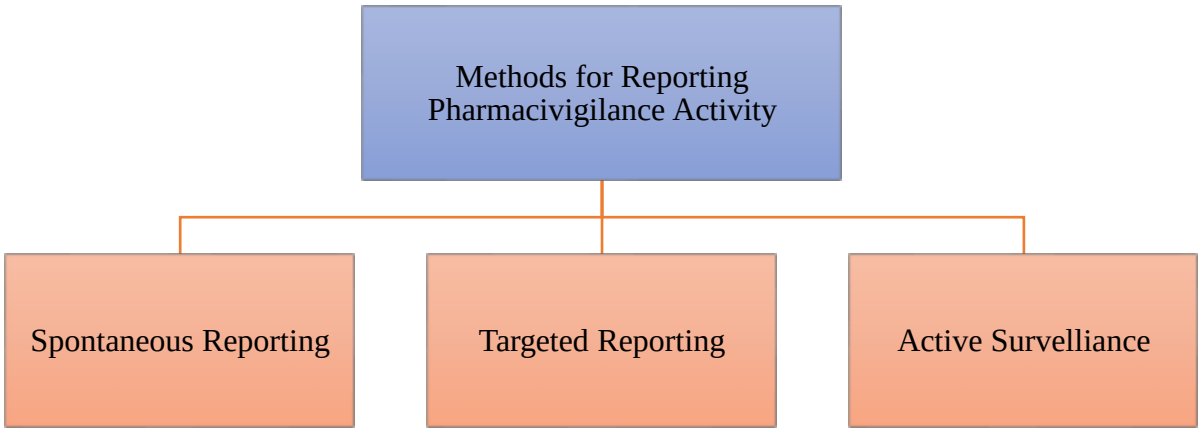
Objectives of Pharmacovigilance:

1. To improve patient care and safety.
2. To improve public health and safety.
3. To contribute to the assessment of benefit, harm, effectiveness and risk of medicines.
4. To promote understanding, education and clinical training

Type or methods of pharmacovigilance:



Components of Pharmacovigilance

1. Adverse Event Case Management including Expedited reporting:
2. Aggregate Reporting:
3. Signal Intelligence; and Risk Management
4. These is the components of Pharmacovigilance which is widely used in the medicinal studies.
5. This study involves details information about those components.

Types of Surveillance Methods:

Pharmacovigilance Program in India (PVPI):

Under the supervision of the Ministry of Health & Family Welfare, Government of India, the Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, works in association with the Department of Pharmacology.

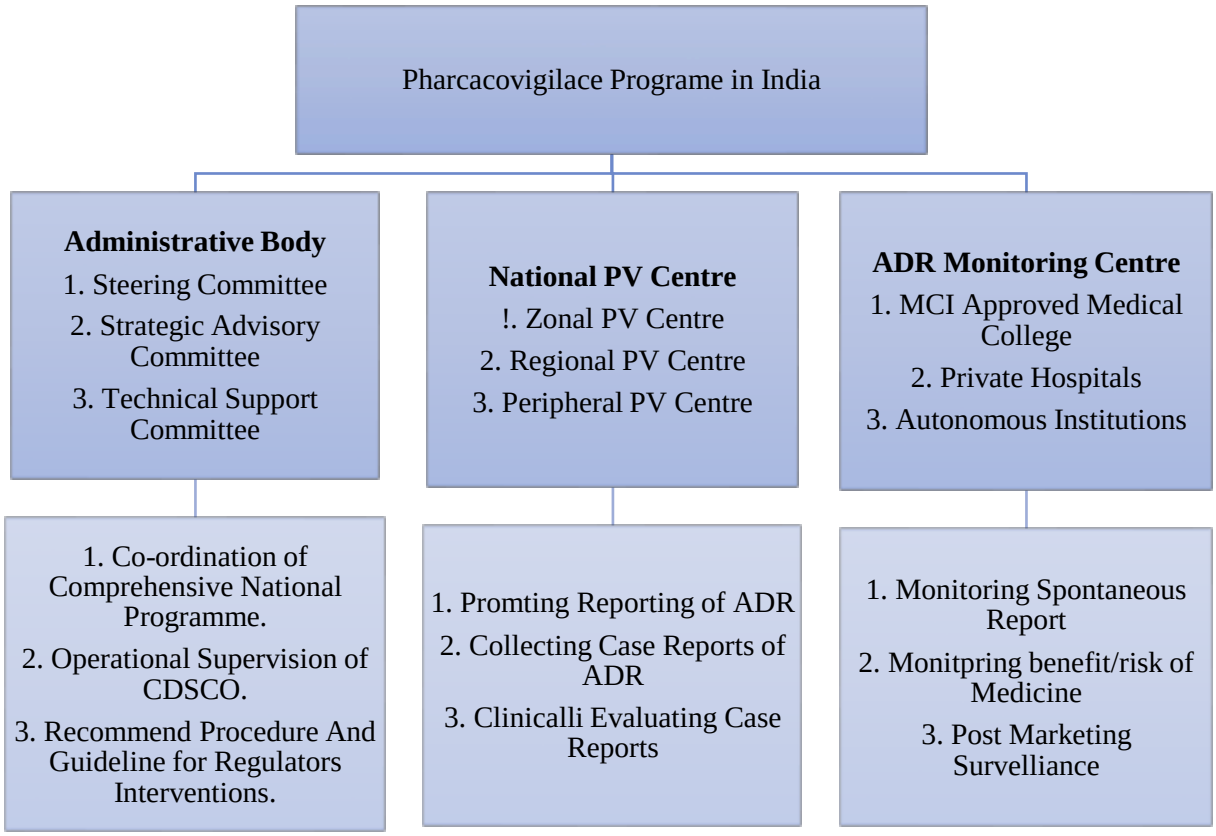
The nationwide Pharmacovigilance program was initiated by the All-India Institute of Medical Sciences (AIIMS), New Delhi, to ensure drug safety and safeguard patient health.

As a National Coordinating Center (NCC), the AIIMS Department of Pharmacology oversees the initiative.

A steering committee will manage the center's operations.

The Indian government's Pharmacovigilance Program of India (PVPI) is responsible for identifying and dealing with issues related to the safety of medications.

The purpose of the Pharmacovigilance Program of India is to collect and analyse data to arrive at an inference to recommend regulatory interventions, besides communicating risks to healthcare professionals and the public.



Objectives of PVPI:

1. To keep updated on adverse drug reactions (ADRS).
2. To raise awareness of the significance of ADR reporting in India among medical professionals
3. To track the medication's benefit-risk profile Provide unbiased, fact-based guidelines for medication safety.
4. Assist the CDSCO in developing regulatory decisions regarding medication safety.
5. Share outcomes with all relevant organizations.
6. Establish a national centre of excellence comparable to those throughout the world.
7. Guidelines for drug safety monitoring.

ADR Monitoring Centres:

1.	Department of Pharmacology & nbs & nbsbep Therapeutics & Toxicology, Govt Medical College, Bakshi Nagar, Jammu
2.	Department of Pharmacology, PGIMER, Chandigarh
3.	Department of Pharmacology. RG Kar Medical College, Kolkata
4.	Department of Pharmacology, Lady Hordinge Medical College, New Delhi
5.	Department of Clinical Pharmacology Seth GS Medical College & KLM Hospital Parel Mumbai
6.	Department of Clinical & Experimental Pharmacology School of Tropical Medicine, Chittaranjan
7.	Department of Pharmacology, JIPMER Pondicherry

8.	Department of Clinical Pharmacy, JSS Medical College Hospital Karnataka
9.	Department of Pharmacology, Medical College Guwahati, Assam
10.	Institute of Pharmacology Madras Medical College, Chennai
11.	Department of Pharmacology, SAIMS Medical College, Indore Ujjain
12.	Department of Pharmacology GSVM Medical College Swaroop Nagar Kanpur, UP
13.	Department of Pharmacology Pandit Bhagwat Dayal Sharma, Post Graduate Institute of Medical Sciences. Rohtak Haryana.
14.	Department of Pharmacology. Dayanand Medical College and Hospital, Ludhiana, Punjab
15.	Department of Clinical Pharmacology, Sher Kashmir institute of Medical Sciences, Srinagar J&K
16.	Himalayan Institute of Medical Sciences, Dehradun, Uttarakhand
17.	Department of Pharmacology, Santosh Medical University Santosh Nagar Ghaziabad
18.	Department of Pharmacology SMS Medical College: Jaipur

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