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An Overview of the Pharmacovigilance in India: From ADR Reporting to Regulatory Action

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Abstract: Pharmacovigilance (PV) is the science and activities concerned with detection, assessment, understanding, and prevention of adverse drug reactions (ADRs) and other drug-related problems, playing an important role in promoting patient safety and rational use of medicines. This review provides an overview of the development and current status of pharmacovigilance in India, from major historical drug-safety events that highlighted the need for systematic ADR monitoring to the development of the present pharmacovigilance system. It discusses the classification of ADRs, the short, medium, and long-term objectives of PV, and the Pharmacovigilance Programme of India (PvPI), including the role and ADR Monitoring Centers in collecting, assessing, and monitoring safety information. The review further describes method of reporting ADR through reporting forms, mobile applications, and helpline along with roles of the Indian Pharmacopoeia Commission (IPC), Central Drugs Standard Control Organization (CDSCO), healthcare professionals, and pharmacists in drug-safety monitoring. Data collection, signal detection, Vigiflow, and regulatory actions based on pharmacovigilance data are also discussed. Despite these developments, challenges such as under-reporting, lack of awareness, shortage of trained personnel, limited resources, inadequate infrastructure, polypharmacy, and drug interactions continue to affect effective pharmacovigilance. Recent developments in digitalization and the use of artificial intelligence may support improved data analysis and earlier identification of potential safety concerns. Strengthening collaboration among regulatory authorities, pharmaceutical industries, healthcare professionals, and patients, together with improved training and reporting practices, is essential for enhancing pharmacovigilance and promoting the safe and rational use of medicine in India.

Keywords: Pharmacovigilance; Adverse Drug Reactions (ADR's), Pharmacovigilance Program of India (PvPI); Indian Pharmacopoeia Commission (IPC); ADR monitoring centers; CDSCO; ADR reporting; ADR detection; Drug safety; Artificial Intelligence; Patient safety; Rational use of medicines.

I INTRODUCTION

A. BACKGROUND

I. INTRODUCTION TO PHARMACOVIGILANCE:

Pharmacovigilance, defined by the World Health Organization as “The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. This may play a vital role in ensuring the safe medication which is relative by patient [2]. Pharmacovigilance helps to ensure the effective use of medicine and safe drugs thereby reduces the

drug-related morbidity and mortality. Pharmacovigilance classifies into two phases

Pre-Marketing Surveillance: ADRs are monitored during preclinical studies, and phases I,II and III are clinical trials done before approval.

Post-Marketing Surveillance: ADRs monitor after the medicine enters into the market through the reports from the patients, Physician, Pharmacist and other healthcare professionals.

Pharmacovigilance also evaluates drug toxicity, effectiveness and interactions. The main objective of Pharmacovigilance is

to enhance patient care, protect public health, and detect medicine-related problems [3].

1. ADVERSE DRUG REACTION (ADR):

An adverse drug reaction (ADR) as a response to a drug that is noxious and unintended and that occurs at doses normally used in man for the treatment, prophylaxis, or diagnosis of disease, or for the modification of physiological function [40].

2. Classification of Adverse Drug Reactions:

2.1. Type A (Augmented)

Type A reactions are dose-related and predictable because they are associated with the known pharmacological action of the drug. They are usually common and may improve when the dose is reduced [14].

Example: Dry mouth with tricyclic antidepressants [16].

2.2. Type B (Bizarre)

Type B reactions are unpredictable and not usually dose related. They are often associated with individual patient susceptibility, such as allergic or idiosyncratic reactions [14]. Example: Malignant hyperthermia associated with general anaesthetics [16].

Allergic reactions: Immune-mediated reactions to a drug, unrelated to its therapeutic action Example: Skin or respiratory allergic reactions [40].

Idiosyncrasy: A genetically determined, abnormal and unpredictable reaction to drug. Example: Primaquine – haemolysis in G6PD deficiency [40].

2.3. Type C (Chronic)

Type C reactions are related to long-term or continuous use of the drug. They usually develop gradually due to cumulative exposure. Example: osteoporosis with prolonged corticosteroid use.

2.4. Type D (Delayed)

Type D reactions occur after a delay following drug exposure and may become apparent only after some time. Examples include Teratogenic and carcinogenic effects.

2.5. Type E (End-of -use)

Type E reactions occur after stopping a drug, particularly following prolonged use. Gradual withdrawal may help reduce these reactions. Example: Withdrawal symptoms after long-term use of certain medicines.

2.6. Type F (Unexpected Failure of Therapy)

Type F reactions occur when a drug fails to produce the expected therapeutic effect, usually due to dose or drug interactions. Example: Oral contraceptives failure with enzyme-inducing drugs as summarized in Figure 1 [16].

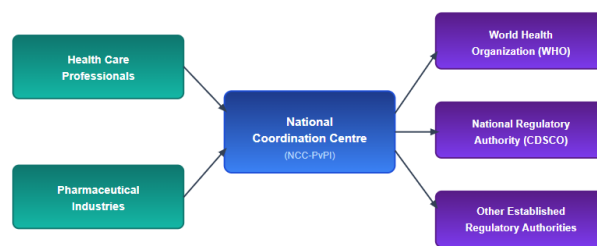


Figure: 1 Diagrammatic Representation of the Pharmacovigilance [39]

II. HISTORICAL BACKGROUND:

Pharmacovigilance has developed through several important events related to ADR and early drug safety events: One of the earliest reported cases involved a patient who causes death after chloroform anesthesia. In 1937, 107 deaths in America were allied with the toxicity of diethylene glycol present in a Sulfanilamide preparation. It caused thousands of birth abnormalities, particularly Phocomelia, and increased miscarriages. Dr. MC. Bride reported on the association between thalidomide use during pregnancy and congenital abnormalities. This tragedy increases the attention of need for strict pre-marketing safety and efficacy testing [4].

III. OBJECTIVES:

- Short Term Objective: To promote ADR reporting and notification among Healthcare Professionals.
- Medium Term Objective: To promote the medical professionals and Non-Governmental Organizations (NGOs) drug safety monitoring ADR surveillance.
- Long Term objective: To achieve operational efficiencies that ensure the rational use of medicines and minimize the risks [17].

IV. IMPORTANCE OF PHARMACOVIGILANCE IN INDIA:

Pharmacovigilance proves to be a vital system for protecting medicine all over a country. It is done with the help of Physician, Nurses, Pharmacist and other Healthcare professionals of the country. The importance of pharmacovigilance is as follows,

- Development of case series.
- Detecting and evaluating the safety signals from spontaneous report.
- Analysis of reported cases.
- Drug safety during clinical trials.
- Observing the safety of drugs/medicines.
- To promote rational and safe use of medicines [19].

Pharmacovigilance is mainly needed to ensure the safe use of drugs [18] (Figure: 2 Pharmacovigilance Programme of India). Continuous drug monitoring of both known and unidentified ADR's is important. This monitoring helps to provide new safety information, identify the risks, and improve the safety profile and proper use of medicines [17].

1961	(Thalidomide Tragedy): Thalidomide was widely used as a sedative and for nausea during pregnancy.
1963	WHO started an international drug monitoring programme to collect and monitor information about ADRs from different countries.
1978	The WHO drug-monitoring programme was moved to Uppsala; Sweden may later become the center for international pharmacovigilance activities.
1996	India started conducting clinical trials according to international standards, supporting better evaluation of medicines.
1997	India became part of WHO ADR Monitoring programme, strengthening its involvement in global drug-safety monitoring.
1998	Pharmacovigilance activities were formally initiated in India to improve the detection and reporting of ADRs.
2000	The Indian Council of Medical Research (ICMR) introduced ethical guidelines for biomedical research involving human subjects.
2001	CDSCO introduced Indian Good Clinical Practice (GCP) guidelines to improve the quality and safety of clinical research.
Current status	Pharmacovigilance has developed into a broader system that includes ADR reporting, safety signal identification, risk assessment, risk management and Post Marketing Surveillance.

Table 1: History and Development.[1]

V. PHARMACOVIGILANCE PROGRAM IN INDIA(PvPI):

India acts as a Drug Hub. India is recognized as the “Global Pharmacy” for Generic Medicines. India is the second most country in the world and also provides 1.35 billion potential

market for the drugs and a value of US \$ 1.4 billion Worth of clinical research [17]. In India, drugs safety monitoring began with WHO participation which has been organized as Programme for Drug Monitoring (PIDM) in 1997. Totally, six regional centers has been established in that only two (Mumbai and New Delhi) has been retained. It leads to poor reporting of adverse events. CDSCO launched PVPI in July 2010. Initially, the All-India Institute of Medical Science in New Delhi act as the National Coordinating Center. To ensure long-term growth, IPC to the role of NCC for PVPI on 15thApril, 2011. The nationwide PV programme coordinated by the IPC as a NCC as depicted in Figure 2 [32].

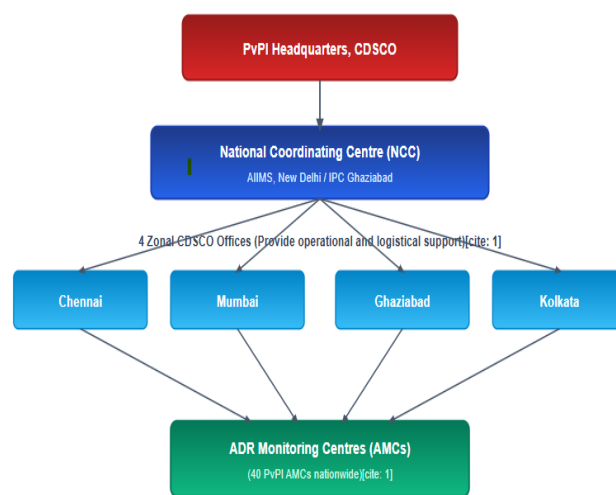


Figure 2: Pharmacovigilance Programme of India [18].

1. ROLES OF PvPI: The main aim of PvPI is to collect the data and to report it. [18] In which the analysed data to arrive at an recommend regulatory actions and communicate the drug related risk to Healthcare Professional and peoples [17].

VI. ADR MONITORING CENTER:

The Adverse Drug Reaction Monitoring Centre (AMC) at JIPMER, functioning under the Pharmacovigilance Programme of India (PvPI), plays an important role in ensuring medication safety through the regular detection and monitoring of ADRs. A study analysed 6007 ADR reports collected from 2010-2020 to assess their characteristics and identify potential safety signals. Anti neoplastic drugs were the most commonly implicated, while skin-related reactions were frequently reported. About 19.2% of ADRs were serious, highlighting the importance of continuous ADR Monitoring and reporting.

Similarly, a retrospective observational study evaluated ADR reports received by an ADR Monitoring Centre during 2010-2020. It assessed patient characteristics, causality, severity and preventability of ADRs, along with possible disproportionate reporting signals. The study highlights the

importance of systematic ADR reporting in identifying potential drug-safety concerns [5].

ADR Monitoring Centre	State
Department of pharmacology, All India Institute of Medical Science	New Delhi
Department of Pharmacology, PGIMER	Chandigarh
Department of Pharmacology, R.G. Kar Medical College	Kolkata
Department of Clinical Pharmacy, JSS Medical College Hospital	Karnataka
Department of Clinical Pharmacology, Lady Hardinge Medical College	Kolkata
Department of Pharmacology, SAIMS Medical College	Indore-Ujjain
Institute of pharmacology, Madras Medical College	Tamilnadu
Government Medical College, Palakkadu	Kerala
Indira Gandhi Government Medical College	Maharashtra
Government Stanley Medical College	Tamilnadu

Table 2: Few ADR Monitoring centers (AMC's) with their states [38].

VII. ADR REPORTING SYSTEM IN INDIA:

India's Pharmacovigilance Programme (PvPI) provides multiple ways for reporting ADRs. ADR reporting forms are available for healthcare professionals and consumers, including versions in several Indian language (Figure 3). ADRs can also be reported through the ADR-PvPI mobile applications, which makes reporting easier and more accessible. In addition, a toll-free helpline allows patients and healthcare professionals to report ADRs verbally, these reporting methods help in collecting ADR information and contribute to better drug-safety monitoring in India [6].

The ADR monitoring system in India is supported by a network of ADR Monitoring Centers (AMCs) located in different medical colleges and hospitals across various states

as shown in Table 2. These centers help in strengthening the collection and monitoring of adverse drug reaction information at the regional level. The collected information is useful for assessing the safety of medicines and identifying possible drug-related safety concerns. This organized monitoring system helps improving pharmacovigilance activities and promotes safer use of medicines in Indian (Figure 4)

The ADR information collected through this system is further evaluated to identify important safety signals associated with medicines. These findings can support regulatory authorities in taking appropriate safety measures and updating information related to the safe use of medicines. This helps to improve patient safety and strengthen the pharmacovigilance system in India [41].

1. HOW TO REPORT:

Suspected ADRs can be reported using ADR reporting forms available for healthcare professionals and consumers. Reports can also be submitted through the PvPI toll-free helpline or the ADR-PvPI mobile application. Consumer forms are available in multiple languages to make reporting easier.

2. WHERE TO REPORT:

ADR reports can be submitted to the National Coordination Centre (NCC-PvPI) or the nearest ADR Monitoring Centre (AMC). Reports received at AMC are reviewed and further processed for safety assessment.

3. WHOM TO REPORT:

Healthcare professionals, patients and consumers can report ADRs to the nearest ADR Monitoring Centre (AMC) or NCC-PvPI. Pharmaceutical companies can also submit individual case safety reports. The submitted information is kept confidential, and reports are assessed by healthcare professionals and pharmacovigilance experts [7].

VIII. INDIAN PHARMACOPOEIA COMMISSION (IPC):

The Indian Pharmacopoeia Commission (IPC) is an important organization involved in maintaining the quality and standards of medicines in India. It works towards establishing proper standards for drug used in healthcare. IPC publishes the Indian Pharmacopoeia (IP), which contains monographs describing important information and quality requirements for drugs. It also contributes to the prepare of the National Formulary of India (NFI), which provides guidance on the appropriate use of medicines for healthcare professionals [8].



SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For **VOLUNTARY** reporting of ADRs by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION (National Coordination Centre-Pharmacovigilance Programme of India)

Ministry of Health & Family Welfare, Government of India, Sector-23, Raj Nagar, Ghaziabad-201002

PvPI Helpline (Toll Free) :1800-180-3024 (9:00 AM to 5:30 PM, Monday-Friday)

Initial Case ☐		Follow-up Case ☐		FOR AMC / NCC USE ONLY																											
A. PATIENT INFORMATION *				Reg. No. / IPD No. / OPD No. / CR No. :																											
1. Patient Initials:		2. Age or date of birth:		AMC Report No. :																											
3. Gender: M ☐ F ☐ Other ☐		4. Weight (in Kg.):		Worldwide Unique No. :																											
B. SUSPECTED ADVERSE REACTION *				12. Relevant investigations with dates : 13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.) 14. Seriousness of the reaction : No ☐ If Yes ☐ (please tick anyone) ☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly ☐ Life threatening ☐ Disability ☐ Hospitalization-Initial/Prolonged ☐ Other Medically important 15. Outcome: ☐ Recovered ☐ Recovering ☐ Not Recovered ☐ Fatal ☐ Recovered with sequelae ☐ Unknown																											
5. Event / Reaction start date (dd/mm/yyyy)																															
6. Event / Reaction stop date (dd/mm/yyyy)																															
7. Describe Event/Reaction management with details , if any																															
C. SUSPECTED MEDICATION(S) *																															
S. No.	8. Name (Brand/ Generic)	Manufacturer (if known)	Batch No. / Lot No.	Expiry Date (if known)	Dose	Route	Frequency	Therapy Dates		Indication	Causality Assessment																				
								Date Started	Date Stopped																						
i																															
ii																															
iii																															
iv#																															
9. Action taken after reaction (please tick)								10. Reaction reappeared after reintroduction of suspected medication (please tick) <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th>Yes</th> <th>No</th> <th>Effect unknown</th> <th>Dose (if re-introduced)</th> </tr> <tr><td></td><td></td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td></tr> </table>				Yes	No	Effect unknown	Dose (if re-introduced)																
Yes	No	Effect unknown	Dose (if re-introduced)																												
S. No. as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown																									
i																															
ii																															
iii																															
iv																															
11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)																															
S. No.	Name (Brand / Generic)	Dose	Route	Frequency (OD, BD, etc.)	Therapy Dates		Indication																								
					Date Started	Date Stopped																									
i																															
ii																															
iii#																															
Additional Information :					D. REPORTER DETAILS *																										
					16. Name & Address : _____																										
					Pin : _____ Email : _____																										
					Contact No- : _____ Signature : _____																										
					17. Date of this report (dd/mm/yyyy) :																										
Signature and Name of Receiving Personnel : _____																															
Confidentiality : The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.																															

Use separate page for more information

* Mandatory Fields for suspected ADR Reporting Form

Figure 3: Suspected ADR reporting form for Healthcare Professional



MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)

Indian Pharmacopoeia Commission, National Coordination Centre- Pharmacovigilance Programme of India,
Ministry of Health & Family Welfare, Government of India.

This reporting is voluntary, has no legal implication and aims to improve patient safety. Your active participation is valuable.

1. Patient Details				
Patient Initials:	Gender (V): Male ☐ Female ☐ Other ☐		Age (Year or Month) :	
2. Health Information				
a. Reason(s) for taking medicine(s)(Disease/Symptoms):				
b. Medicines Advised by (V): Doctor ☐ Pharmacist ☐ Friends/Relatives ☐ Self (Past disease experienced/No past disease experienced) ☐				
3. Details of Person Reporting the Side Effect				
Name (Optional):				
Address:				
Telephone No:			Email:	
4. Details of Medicine Taking/Taken				
Name of Medicines	Quantity of Medicines taken (e.g. 250 mg, Two times a day)	Expiry Date of Medicines	Date of Start of Medicines	Date of Stop of Medicines
			dd/mm/yy	dd/mm/yy
			dd/mm/yy	dd/mm/yy
			dd/mm/yy	dd/mm/yy
Dosage form (V) : Tablet ☐ Capsule ☐ Injection ☐ Oral Liquids ☐ If Others (Please Specify.....)				
5. About the Side Effect				
When did the side effect started?		Side Effect Continuing (Yes/No): ☐		
When did the side effect stopped?				
6. How bad was the Side Effect? (Please v the boxes that Apply)				
☐ Did not affect daily activities		☐ Affect daily activities		
☐ Admitted to hospital		☐ Death		
☐ Others				
7. Describe the Side Effect (What did you do to manage the side effect?)				
The information provided in this form will be forwarded to ADR Monitoring Centre for follow-up. You are requested to cooperate with the programme officials when they contact you for more details. Please do report if you do not have all the information.				

Figure 4: ADR reporting form for consumers

1. ROLES OF IPC in drug safety:

- IPC play an important role in drug safety and Pharmacovigilance in addition to setting drug standards.
- It regularly updates drug standards by adding new monographs and revising existing ones.
- IPC provides IP Reference Substance (IPRS) for drug identification and purity testing.
- It acts as the National Coordinating Centre (NCC) for the Pharmacovigilance Programme of India (PvPI).
- It coordinates the collection and monitoring of ADR reports through ADR Monitoring centers across the country.
- IPC also supports the Materiovigilance Programme of India (MvPI) and Haemovigilance Programme of India (HvPI).
- Through these activities, IPC supports CDSCO in making decisions related to the safe use of medicines and promotes patient safety in India [9].

IX. CENTRAL DRUG STANDARD CONTROL ORGANISATION(CDSCO):

The Central Drug Standard Control Organization (CDSCO) is the most primary regulatory body in India. CDSCO is under the ministry of Health and Family Welfare headquartered in New Delhi and it is headed by Drug Controller General of India (DCGI). CDSCO mainly responsible to ensure safety, efficacy and quality of drugs, cosmetics, medical sciences and biological products. CDSCO establishes nationwide network of ADR Monitoring Centers (AMCs). It also creates awareness and training programs for Healthcare Professionals [33].

1. ROLES OF CDSCO IN PV:

CDSCO is responsible to ensure the approval processes for new medicines, regulate clinical trials in India. They collaborate with state control organizations to ensure proper regulatory supervision [38]. It also plays a crucial role in PV in India by ensure continuous monitoring the safety of medicinal products after they released in the market [33].

X. ROLE OF PHARMACIST IN ADR REPORTING:

The pharmaceutical care was driven by the mass-produced medicines, increase poly pharmacy, drug safety events such as the thalidomide tragedy. It enhances the need of pharmacists to focus not only on supply of medicines but also overall medication-use process. This approach emphasized in identifying, preventing, drug related problems and linking pharmacy practice with the objective of pharmacovigilance.

Pharmacy education incorporated clinical sciences such as Pharmacology, Pharmacotherapy, Pathophysiology and patient assessment. The PharmD degree further strengthened or enhanced the clinical role of Pharmacists. These developments involve the pharmacist as important participant in patient safety and pharmacovigilance activities [30]. One of the primary roles of Clinical Pharmacist in PV is to detect, and report ADR. Timely reporting of ADR improves drug safety surveillance. Clinical Pharmacist contributes to PV by assessing the causality, severity, and preventability of ADR using standardized tools which improve quality of ADR reports. Clinical Pharmacists also collaborate with physicians, nurses and other Healthcare Professionals to promote the safety of medication. They are involved in PV awareness, training to improve ADR reporting and medication safety processes [31].

XI. DATA COLLECTION, ANALYSIS AND SIGNAL DETECTION:

Signal detection is important component of Pharmacovigilance which has potential link between adverse event and drugs. Many systematic approaches have been used to detect the safety signals from spontaneous ADR reports. It includes proportional reporting methods, Bayesian approaches, and other statistical signal detection techniques. Data mining is also used to determine the potential Drug-Drug interaction. Modern software and digital systems can assist for collecting and analyzing the data sets and determining the usage of drugs in various disease, medication errors, drug interaction and other factors associated with ADR [22].

1. VIGIFLOW(INDIA):

Vigiflow is a web-based individual case report (ICSR) management system, which is designed for electronic collection, documentation, processing and managing the suspected ADR reports. It is developed and it is maintained by Uppsala Monitoring Center (UMC), Sweden. Vigiflow follows ICH E2B standard and it is the trademark of the UMC. In India, Vigiflow is used under PvPI for managing and processing ADR data/ ICSR data [39] (Figure 1).

XII. REGULATORY ACTIONS BASED ON PHARMACOVIGILANCE DATA:

Signal detection: Pharmacovigilance data mainly helps in identifying possible safety signals from reported adverse drug reactions. These signals indicate that medicine may have an unexpected safety concern.

Signal Assessment: The identified signals are further assessed using clinical information and other available safety data. This helps to determine whether the signal is strong enough to require further action [10].

Regulatory Decision: When a safety concern is confirmed, regulatory authorities evaluate its effect on the medicine benefit-risk balance and decide the appropriate action [11].

Regulatory actions: Depending on the risk, actions may include updating product information, modify the Risk Management Plan, or introduce additional risk-minimization measure [12].

Safety Monitoring: After taking regulatory action, the medicine continues to be monitored to check whether the safety concern is controlled and whether further action is needed [11].

XIII. CHALLENGES OF PHARMACOVIGILANCE IN INDIA:

Pharmacovigilance progress face several challenges that can act as major drawback for effective detection, reporting, assessment and prevention of Adverse Drug Reaction (ADRs). Major challenges include,

- A shortage of trained and dedicated staff and skilled personnels in pharmacovigilance.
- Poor financial resources.
- Institutional /Political influences may create difficulties in creating the effectiveness of pharmacovigilance programs.
- Lack of awareness about ADR reporting among Health Care Professionals.
- Poly- pharmacy and drug interactions [19].

The other challenges include inadequate infrastructures, delay in updating regulatory guidelines, limited implementing of PV inspections, and conservative approaches toward New Drug Research. Another important challenge is failing to recognize ADR in a timely manner particularly during hospital admission. Patients' self-medication and switching between Prescription Only Medicines (POM) and Over the Counter (OTC) medicines may further increase the adverse effects [22].

ADR is most common impact on patient health, and includes decreased quality of life, increased hospitalizations, and also increased in mortality rates [24].

XIV. RECENT DEVELOPMENT AND FUTURE PERSPECTIVE:

1. DIGITALISATION OF PHARMACOVIGILANCE:

India has increasingly adopted digital methods for ADR reporting and safety- data management. These developments have made reporting and collection of Pharmacovigilance information more efficient [13].

2. STRENGTHENING DRUG SAFETY MONITORING:

Artificial Intelligence technological developments can support faster detection and evaluation of safety problems, helping Pharmacovigilance systems respond more effectively to emerging risks [15].

3. ROLE OF AI IN PHARMACOVIGILANCE:

The advancement in AI involves enabling the transition from reactive to more proactive surveillance approaches. This active surveillance involves systemic collection and analyzing the safety data throughout a lifecycle [23].

4. FUTURE PERSPECTIVE:

Future Pharmacovigilance in India is expected focus on better integration of drug-safety monitoring into routine healthcare, improved data analysis and a more proactive approach to patient safety [13].

XV. CONCLUSION:

PV plays a significant role to ensure safety of the medication and to protect the public health in India. With India's growing Pharma industries and Clinical research activities and drug safety monitoring has been frequently increased. The PvPI coordinated by the IPC has increased and strengthened monitoring the ADR and challenges such as under reporting and limited awareness. The PV in India has enhanced the drug safety monitoring and development. The PV system is necessary to improve detection, assessment and prevent adverse drug reactions. The new drug products provide various benefits to the individual and public health. The improvement of signal detection, analysis and assessment of safety reports can help the early detection of potential adverse drug reactions. The future of PV in India depends on improvement of collaboration among industries, healthcare professionals and patient is important to identify the early risk and to prevent the adverse drug reactions. Improvement of healthcare professional training, improving regulatory reporting practices and the patient participation is important for developing an effective PV system. Continuous monitoring and proper evaluation of safety signals and appropriate regulatory interventions can help ensure that benefits of medicines reduce the risk and improve the safe and rational use of medicines.

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