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REVIEW ARTICLE

An Integrated Review of Pharmacovigilance, Materiovigilance, and Hemovigilance Programs in India: Evolution, Implementation, and Impact on Patient Safety

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ABSTRACT

The drug development process is complex, with a central focus on ensuring quality, safety, and efficacy. Despite rigorous clinical trials, adverse drug reactions (ADRs) often become apparent only after widespread clinical use, making post-marketing surveillance and pharmacovigilance essential components of patient safety. The prevalence of ADRs is amplified by factors such as polypharmacy and age-related physiological changes, contributing significantly to hospitalizations and healthcare expenditures. Although ADR reporting practices in India have recently been revised, reporting rates remain lower than those observed in high-income countries. This review provides a comprehensive overview of the evolution, structure, and current practices of pharmacovigilance in India, with particular emphasis on the roles of the Pharmacovigilance Programme of India (PvPI), as well as emerging initiatives such as materiovigilance and hemovigilance. The paper highlights the importance of robust ADR monitoring systems, regulatory frameworks, and public awareness in enhancing patient safety and improving therapeutic outcomes.

Keywords: pharmacovigilance, programme of India, national coordinating center, adverse drug reactions, materiovigilance, hemovigilance.

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1. INTRODUCTION

Pharmacovigilance (PV) is the branch of science that deals with the detection, assessment, understanding, and prevention of adverse drug reactions. The term "pharmacovigilance" is derived from Greek. PV aims to work globally to monitor the risk/benefit ratio and improve patient safety and quality of life. For the first time, an Australian physician and obstetrician, William McBride, wrote a letter to The Lancet journal about his findings on rare congenital disabilities, such as shortened or absent limbs, in babies born to mothers who had taken thalidomide for morning sickness (1). A retrospective study conducted in 1973 confirmed that prenatal exposure to thalidomide was linked to an increased risk of congenital disabilities (2). McBride's warning concerning thalidomide teratogenicity saved many babies from birth defects and emphasized the necessity for an efficient PV system to address such adverse events (3).

In 1957, the German pharmaceutical company Chemie Grünenthal manufactured thalidomide under the trade name Contergan, a medication for anxiety, insomnia, and morning sickness. However, it was not tested in pregnant patients. Within four years, the drug was approved in Africa, Europe, and Canada. It was initially considered safe for pregnancy, but concerns about birth defects emerged in 1961, leading to its removal from the European market that same year. In 1968, the World Health Organization launched a "Program for International Drug Monitoring" with ten nations, including Germany, Canada, Ireland, Sweden, Denmark, New Zealand, and the Netherlands. In 1971, an international database was established in Geneva and later transferred to Uppsala, now known as VigiBase.

It was intended to centralize adverse drug reaction data worldwide, enabling earlier detection of PV signals to improve patient care and medication safety. However, other factors, such as genetics and drug interactions, which are not studied during clinical trials, also increase the risk of adverse drug reactions (4). The objective of this review is to critically analyze the development, structure, and effectiveness of pharmacovigilance, materiovigilance, and hemovigilance programs in India and to identify key challenges and opportunities for improving patient safety. In this review article, we describe key events that led to the evolution of pharmacovigilance.

2. WHY IS PHARMACOVIGILANCE NECESSARY?

Medicines have significantly improved patients' lives by controlling and managing diseases. However, they can also cause adverse effects, which may increase the risk of morbidity and mortality. ADRs are the tenth leading cause of death and morbidity worldwide. Global studies reveal that ADRs account for 3–7% of all hospitalizations, with 10–20% occurring in inpatients (5). Only one in every twenty ADRs is recognized and classified as a genuine side effect, which leads to the false conclusion that the incidence of adverse reactions is much lower than it actually is (6) ADRs increase both the risk of injury and the cost of hospitalization, imposing an additional burden on the national healthcare system [6]. Serious ADRs are the sixth leading cause of mortality among hospitalized patients in the United States. Prolonged hospitalization doubles treatment costs. Therefore, healthcare teams and patients share the goal of early detection and prevention of ADRs. In developing nations, there is limited information on drug safety in patients. The critical questions related to drug safety concerns often do not arise during clinical trials. Well-structured clinical trials for new medications are performed on homogeneous groups of carefully screened and preselected patients. It is important to note that although all human medications undergo preclinical and clinical testing, safety concerns may still arise during clinical trials.

Genetic variables and drug interactions, which are not always investigated in clinical trials, can increase the likelihood of adverse drug reactions (2). It is widely expected that drugs undergo several phases of clinical trials before being released to the market. However, clinical trials have limitations, as they often exclude special groups such as children, pregnant women, and the elderly, **e.g.,** children, pregnant women, and geriatrics. Studies with limited sample sizes, diverse ethnic groups, varying genetic compositions, and short trial durations may fail to demonstrate the true effectiveness of the drug. Additionally, toxicity observed in animal trials is not always a good predictor of similar effects in humans (3). In this review article, we describe some of the events that led to the evolution of pharmacovigilance.

Pharmacovigilance Programme (PvPI) in India

The Central Drugs Standard Control Organization (CDSCO) provides financial and administrative support to all ADR monitoring centers. CDSCO is a regulatory body established under the Drugs and Cosmetics Act of 1940, which governs both central and state governments. According to this act, drugs and health are included in the concurrent list of the Indian Constitution. CDSCO has six zonal offices, four sub-zonal offices, and seven laboratories under its control [7]. It collaborates with state drug authorities to ensure uniform enforcement of the Drugs and Cosmetics Act.

Its roles include: controlling and regulating the import of drugs, approving clinical trials for new drugs, establishing standards for drugs, cosmetics, diagnostics, and devices, banning drugs and fixed-dose combination drugs, regulating the manufacture and distribution of drugs to ensure safety and quality, serving as a consultative committee and technical advisory board (DTAB) for drug license approval, monitoring pharmacovigilance activities for drugs and vaccines after post-license submission, and publishing the Indian Pharmacopoeia.

Table 1. Timeframe for reporting serious adverse events to CDSCO.

S.no	Reporter	Report to	Time frame for reporting
1	Principal investigator	Central Drug Safety Control Organization(CDSCO) Institutional Ethical Community Sponsor.	Within 24 Hours
2	Sponsor investigator CDSCO	Central Drug Safety Control Organization(CDSCO),Institutional Ethical community Institutional Head.	Within 14-Calendar days.
3	Institutional Ethical community (IEC)	Central Drug Safety Control Organization (CDSCO)	Within 30- Calendar days.
4	Expert committee		Within 30- Calendar days.

India joined the WHO International Drug Monitoring Programme in 1998, but the initiative was initially unsuccessful. In 2005, a nationwide pharmacovigilance programme was established, and in 2010 it was renamed the Pharmacovigilance Programme of India

(PvPI), with the aim of safeguarding the health of the Indian population by ensuring that the benefits of medicines outweigh their risks. The program was relaunched in July 2010 in coordination with AIIMS, New Delhi, with 22 ADR monitoring centers. AIIMS served as the National Coordination Centre (NCC) for monitoring all adverse drug reactions in the country, under the Ministry of Health and Family Welfare. In April 2011, the Indian Pharmacopoeia Commission (IPC) was designated as the National Coordinating Center (NCC). From July 2017, the NCC center was established in Ghaziabad to maintain and develop an ADR database for all medicines used in the Indian population and to become a WHO collaborating center for pharmacovigilance in health programs.

PVPI ADR Monitoring Center

PVPI collects ADR reports according to standard operating procedures (SOPs). Reports submitted through VigiFlow are pooled into a global database at the Uppsala Monitoring Centre in Sweden. ADR monitoring centers must follow SOPs when reporting ADRs to the National Coordinating Center for signal detection.

The primary responsibility of PVPI is to assess causality and approve ADRs, which are then submitted to CDSCO for regulatory decisions on drug safety, including changes to drug labeling to safeguard public health. Currently, 1050 AMC centers operate under PVPI. India ranks 8th in ADR reporting and contributes only 2% to the WHO Individual Case Safety Report (ICSR) database. The overall completeness score for individual case safety reports submitted to the National Coordinating Center PVPI is 0.8 out of 1. ADR AMCs are also responsible for training, sensitizing, and educating physicians through newsletters from PVPI NCC.

Autonomous Institutions and Its Functions - Public Health Program, collecting ADR reports, reporting data to CDSCO headquarters , performing follow-up checks for completeness as per SOPs.

PVPI National Coordinating Center (PVPi NCC), AIIMS New Delhi Roles and Responsibilities: preparing SOPs, guidance documents, and training modules, collecting data, processing it for completeness, and conducting causality assessments as per SOPs, conducting training workshops in all enrolled centers, analyzing PMS, PSUR, and AEFI data received and reporting to CDSCO headquarters.

Adverse Events

The development of new therapeutics positively impacts public health. However, these benefits are accompanied by increased risks, primarily due to adverse drug events (ADEs), which are the most common cause of medical harm to patients. ADEs may be preventable or non-preventable, but the majority are preventable. ADEs are a major global health concern, with variable incidence rates reported in different studies. For example, the incidence is 29.9% in Japan, 8.5% in Saudi Arabia, and 25% in Uganda (9). These variations may be due to different strategies employed in reporting ADEs. Causality assessment methods are used to determine the relationship between a drug and the occurrence of events and may include expert opinion, algorithms, and probability assessments.

The expert opinion method is subjective, based on individual judgment, and has lower reproducibility. The algorithm method is more standardized than expert opinion. However, several scales are available for causality assessment. Due to their complexity and time-consuming nature, their use in clinical practice is limited (10). The WHO–UMC scale and Naranjo scale are the most widely used for assessing ADEs in India and internationally (11). Algorithm scales include the WHO Uppsala monitoring center (WHO- UMC) causality categories (12) Karch & Lasagnas scale (13) a) Naranjo Algorithm Scale b) Naranjo Algorithm Probability Scale (14) Kramer Scale (15).

Table 2. Time frame for submission of individual case safety reports.

S.no	**Cases**	**Time frame for reporting**
1	Death/life threating cases	Within 7 calendar days to Health authorities\ National competent authority (19).
2	Unexpected serious adverse event	Within 14-Calendar days of becoming awareness of serious ADR in India. 15 days in other countries (19).
3	Clinical trials/Safety issues/ serious cases	Within 15- Calendar days.
4	Post marketing cases	Within 15- Calendar days.
5	Non serious cases	With 90-Calendar days of became awareness of adverse event. To European union health authorities Note; Not mandatory for non-EU countries.

VigiBase is a global database that collects data on drugs signaling harm and guides safer use. Currently, there are 35 million anonymized reports of suspected adverse effects recorded. The WHO-UMC in Sweden developed VigiFlow, a web-based management system that coordinates with national centers to track ADRs/ADEs. It is faster and more efficient, improving the quality of reporting. In VigiFlow, data is entered manually using WHO-DD and WHO-ART and saved in VigiBase (16).

VigiBase is the WHO's largest and most comprehensive database, with 30 million reports of suspected ADRs from all member nations since 1968 (17). It serves not only as a database but also as a quality assurance tool linked to various medicines and drug classifications maintained by UMC. It allows data to be entered in a structured format, making retrieval and analysis easier (18).

3. MATERIOVIGILANCE PROGRAMME OF INDIA (MVPI)

The Materiovigilance Programme of India was launched by the Ministry of Health and Family Welfare, Government of India, on June 6, 2015, to monitor the safe use of medical devices nationwide, in association with PVPI. In 2017, the Government of India issued the Medical Devices Rules to regulate medical devices in the country. In 2018, the Sree Chitra Tirunal Institute of Medical Sciences was recognized as a national collaboration center, and the National Health System Resource Center (NHSRC), Delhi, acts as a technical support partner, while CDSCO functions as the national regulator. The medical device act has existed since 1 January 2018 (20). The Indian Pharmacopoeia Commission works in association with the National Coordinating Center (NCC) to recruit and develop manpower for all MvPI activities : data collection and analysis, signal detection, analyzing outcomes, and communicating with CDSCO for regulatory action, the Indian Pharmacopoeia Commission is the sole custodian for maintaining the MvPI database, IPC issues medical device alerts to raise awareness. IPC provides financial support to the National Collaboration Center (Sree Chitra Tirunal Institute for Medical Science and Technology, SCTIMST) and the Technical Support and Resource Center (National Health System Resource Center, NHSRC)

SCTIMST functions as an institute of national importance under the Department of Science and Technology and emphasizes the development of facilities that are not readily available elsewhere in the country (21).

For example, interventional radiology, cardiac electrophysiology, and new biomedical devices. NHSRC is a national health system resource center established by the National Health Mission (NHM), Ministry of Family Welfare. The healthcare technology division of NHSRC serves as a World Health Organization collaborating center for medical device priorities

Medical devices are instruments, apparatus, or implantable materials that are used alone or in combination, including software or accessories, intended by the manufacturer to be used for humans or animals.

Table 3. Medical devices risk-based classifications –CDSCO.

Category and Level of Risk	Device Examples
Class A - Low risk	Cotton wool, surgical dressing ,alcholol, swabs
Class B -Low moderate risk	Thermometer, BP monitoring devices etc.
Class C -Moderate risk	Implants ,Catheter etc.
Class D- High risk	Angiographic guide wire, heart valve.

Table 4. Timeline for reporting MDAE Event.

Reporting authority	Event (What to be reported), Guidance Document MvPI Version 1.2	To whom	Time line (Time frame)
Manufacture /Importer	Any serious events including death, serious injuries, malfunction of devices/ appliances any recall.	1.National regulatory body. 2.NationalCoordination centre IPC (Indian Pharmacopeia commission).	Event should be reported within 15-Calendar days after becoming awareness of an event (21).
User facilities	Death, Serious injuries, malfunction	1. National regulatory body. 2.National Coordination centre BIPC (Indian pharmacopeia commission). 3.Marketing authorization holder.	1. In case of non-serious events should be reported within 30-Calendar days of awareness, of the event. 2. Within 15 -Calendar days of becoming aware of an adverse event (21)

Hemovigilance Programme of India (HvPI)

The National Institute of Biologicals (NIB) launched the Hemovigilance Programme of India (HvPI) on December 10, 2012, as a key component of the Pharmacovigilance Programme of India (PvPI). The program is designed to document and monitor adverse drug reactions (ADRs) and events related to the transfusion of blood and blood products. Hemovigilance involves the continuous collection and analysis of data on transfusion-related adverse reactions, with the goal of understanding their causes and outcomes to prevent future occurrences.

As the national coordinating center, NIB maintains comprehensive data on all ADRs and adverse drug events (ADEs) associated with blood transfusions (13). The program's main objectives are to raise awareness among healthcare professionals, monitor transfusion reactions, and provide evidence-based recommendations to the Central Drugs Standard Control Organization (CDSCO) to support safety-related regulatory decisions.

Adverse Event Following Immunization

Adverse events following immunization (AEFI) were first documented in India in 1988 and the guidelines were revised in 2005, 2010, and 2015. National AEFI guidelines were developed to provide information to healthcare providers at the national, district, and block levels (23**).**

Table 5. Timeline for reporting AEFI Event.

	Time lines
CRF – Prepared by the medical officer has to send to the district immunization officer (DIO).	
In the next 24 hours, DIO verify and send it to the state and NRHM (HMIS).	Within 24 hours.
National Rural Health Mission (NRHM Health Management Information System (HMIS), etc.	Serious or minor adverse report within a monthly report.

As per the new guidelines, any unwanted medical occurrences following immunization do not necessarily have a causal relationship with the use of vaccines. On the other hand, serious and minor adverse events following immunization, from the point of occurrence to the national level, are mainly reported through monthly progress reports. Minor AEFI occurs a few hours after injection; these are self-limiting and pose little danger. When a minor AEFI increases in severity, it can result in disabling and, rarely, life-threatening outcomes. Serious reactions (AEFI) can result in hospitalization, prolong an existing or significant disability, or cause a congenital anomaly. For example, the BCG vaccine can result in fatal dissemination of BCG infection within 1–12 months.

The oral polio vaccine can result in vaccine-associated paralytic poliomyelitis (VAPP) within a 4–30-day interval. The DTwP vaccine can cause prolonged crying and seizures within 0–24 hours.

Tools for Reporting Adverse Events Following Immunization: AEFI Register: Maintained to record adverse events.. In case of serious adverse events following immunization (AEFI), the form can be obtained from the ADR monitoring centers (AMC).

Case Reporting Form (CRF): Captures essential information such as patient demographics, vaccine details, symptoms, and timeline of events.

Case Investigation Form (CIF): Contains laboratory investigations, medical records, and causality assessments that accompany the AEFI report.

Verbal Autopsy Report: A post-mortem report is prepared in case of death following immunization: adverse events following immunization are categorized as minor, severe, or serious, minor AEFI occurs a few hours after injection - there are self-limiting and pose little danger. When a minor AEFI increases in severity, it can result in disabling and, rarely, life-threatening outcomes. Serious reactions (AEFI) can result in hospitalization, prolong an existing or significant disability, or cause a congenital anomaly. For example, the BCG vaccine can result in fatal dissemination of BCG infection within 1–12 months. The oral polio vaccine can result in vaccine-associated paralytic poliomyelitis (VAPP) within a 4–30-day interval. The DTwP vaccine can cause prolonged crying and seizures within 0–24 hours [24].

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ADR Reporting System in India

The Central Drugs Standard Control Organization (CDSCO) of India will make recommendations based on **:** the signal panel review board and steering committee of the national coordinating center, periodic safety update report, CDSCO uses evidence-based information to make decisions such as issuing drug alerts, banning drugs, and updating package inserts and the safety drug authority in India monitors ADR as per Section 28, schedule M of the Act, and forwards it to PVPI.

Patients are the end-users of medicines and have the fundamental right to report adverse effects or side effects they experience during drug therapy. Various countries attempt to capture the patient's unique experience and perception of drugs, encouraging reporting through multiple systems, including spontaneous reporting and online data submission[25]. In India, there is a spontaneous reporting system for healthcare professionals to submit ADRs. They are encouraged to submit ADRs by filling out the 'Red Form' available at www.ipc.gov.in and www.cdsco.nic.in.Currently, 346 ADR reporting centers report ADRs to the National Coordinating Center (NCC). While there are various procedures/forms in Western countries in ADR reporting, in India, they have a spontaneous reporting system without mandatory legal.

In India, the reporting rate of adverse drug reactions (ADRs reported per million population) has almost doubled over the past three years to 40. Still, it is less than 130, the average rate of ADRs reported for high-income countries, and is disproportionate to the Indian population. According to Dr. Y.K. Gupta, ADR reporting to drug authorities allows for informed decisions on drug usage and utilization of global evidence and ensures that ignoring India’s ADR data does not make drugs more unsafe, as ancestry may respond differently to medications. The invention of medicine has caused enormous changes in individuals through disease control and management. It provides several advantages, but adverse events may cause illnesses, disabilities, or even death.

Besides, patients may experience unpredictable adverse drug reactions with certain drugs. Selection of the appropriate, safest drug for an individual requires skill for a practitioner. In India, a significant portion of the population uses self-medication, increasing the risk of adverse drug reactions. This can be prevented by motivating the public. Previous studies have concluded that public involvement in ADR reporting has a significant impact on ADR reporting rates.

Table 6. International Comparison of Pharmacovigilance Systems.

Aspect	India (PvPI)	United States (FDA/FAERS)	Europe (EMA/EudraVigilance)
Regulatory Authority	CDSCO, IPC	FDA (FOOD and drug administration)	EMA
Reporting System	VigiFlow (WHO-based)	MedWatch, FAERS(FDA adverse event reporting system)	EudraVigilance
Mandatory Reporting	Recently for MAHs(Market Authorization Holders).	Mandatory for manufacturers; Voluntary for HCPs/patients	Mandatory for MAHs, HCPs, and patients
Public Data Access	Limited	Broad(FAERS database)	Broad (Eudra Vigilance database)
Integration with Pharmacovigilance Systems with Electronic Health Records (EHRs)	Integration of EHRs Emerging	Advanced(Sentinel Initiative)	Advanced
Patient Reporting	Available, limited use	Widely promoted	Widely promoted
Signal Detection	Centralized (PvPI)	Centralized, AI-supported	Centralized, Pharmacovigilance Risk Assessment committee (PRAC)

India’s vigilance systems have made notable progress in establishing a framework for monitoring the safety of drugs, medical devices, and blood products. However, compared to international counterparts, challenges remain—particularly in underreporting, data transparency, and integration with clinical practice. Addressing these gaps through mandatory reporting, digital innovation, and enhanced training will be crucial for India to achieve global standards in patient safety and pharmacovigilance effectiveness.

Table 7. Resources in educating patients on ADR reporting.

1	Scientific journals	National coordinate center (NCC) publishes original and review articles on PvPI in national and international journals.
2	Pharmacovigilance Week	17-23 September. Every year, to ensure communication and knowledge enrichment to various stakeholders on medicinal products for the ultimate benefit of patients.
3	Toll-free helplines	1800 180 3024
4	Newsletter	Quarterly
5	E-mail id	Pvpi.compat@gmail.com
6	ADR forms can also be downloaded from the official website.	www.ipc.gov.in
7	Red form 'Suspected adverse drug reaction reporting.	For health care professionals
8	Blue form "Medicines Side Effect Reporting form."	For patients/consumers

4. CONCLUSION

Pharmacovigilance in India has made significant paces with the establishment of AMC, materiovigilance, and hemovigilance centers, and by coordinating with regulatory authorities and healthcare professionals and conducting public health programs, there is a significant improvement in detecting, assessing, and preventing adverse events. However, underreporting, limited awareness, and the need for continuous training are the major setbacks. However, to further strengthen PvPI, adopting teamwork among stakeholders, enhancing reporting systems, and promoting active participation from healthcare providers and patients is essential. A constant commitment to education, technological advancement, and regulatory support will ensure medication and device safety, ultimately safeguarding public health and improving patient outcomes in India.

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