



Drug Safety and Pharmacovigilance in India: Current Status and Future Prospects

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Abstract

Pharmacovigilance (PV) is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. With the growing complexity of drug therapy, PV has become an essential component of public health to ensure the safe and rational use of medicines. This review highlights the history, objectives, processes, methods, challenges, and future perspectives of pharmacovigilance, with special reference to its global and Indian context.

In the scenario of ever-increasing range and potency of medicines, safety of medicines is one of the key parameters along with therapeutic efficacy for success of any drug. India is now a preferred clinical trials destination for to be launched drug entities. By keeping in view the increasing incidences, drug related mortality, proper identification, reporting, evaluation and understanding of adverse drug reaction lead to development of pharmacovigilance. It is a branch of pharmacological science critical to effective clinical practices and public health with immense capability for growth. These necessities the utmost need of effective regulations for drug approval and conscious pre and post approval vigilance of undesired effect especially in India. This article summarizes aims, objectives and methodologies used in pharmacovigilance with a critical overview of existing pharmacovigilance system in India, challenges to overcome and future prospects with respect to Indian context.

Keywords: Adverse drug reaction, Clinical trial, Drug safety, Pharmacovigilance, Post marketing surveillance.

1. Introduction

Pharmacovigilance (PV) is the clinical and pharmacological science dedicated to the detection, assessment, understanding, and prevention of adverse effects and any other medicine-related problems. Derived from the Greek word *pharmakon* (drug) and the Latin word *vigilare* (to keep watch), it operates as a continuous safety net across the entire lifecycle of a pharmaceutical product. While prospective clinical trials are essential to gain initial marketing authorization, they possess inherent blind spots: they test candidate molecules on limited, highly selected cohorts over relatively brief durations under strict supervision. In contrast, post-marketing real-world usage exposes the medication to diverse patient populations, including the elderly, infants, pregnant individuals, and patients with complex co-morbidities taking multiple concurrent therapies. Consequently, pharmacovigilance exists to capture rare, delayed, or unexpected toxicities—such as an adverse event occurring in only one out of every ten thousand patients—that would inevitably slip past standard pre-approval studies.

Historically, modern pharmacovigilance arose directly from major public health catastrophes. The 1937 sulfanilamide disaster in the United States, where an untested toxic solvent (diethylene glycol) resulted in the deaths of over one hundred people, sparked the requirement that medicines must be proven safe before release. Two decades later, the global thalidomide crisis of the late 1950s and early 1960s exposed the catastrophic potential of teratogenic compounds when thousands of children were born with severe phocomelia (limb malformations) after their mothers took the drug for morning sickness. This international tragedy prompted the World Health Assembly in 1963 to establish rapid global data exchange, eventually leading to the creation of the World Health Organization (WHO) Programme for International Drug Monitoring in 1968. Since then, the discipline has transformed from reactive tragedy management into an organized, proactive global architecture.

To understand the core mechanisms of this field, students must distinguish between its fundamental operational terms. An adverse event (AE) refers to any untoward medical occurrence in a patient administered a therapeutic product, regardless of whether a causal relationship exists. When scientific evaluation suggests a plausible causal link between the drug and the noxious,

unintended event at normal doses, it is classified as an adverse drug reaction (ADR). When an event results in death, is life-threatening, requires inpatient hospitalization, causes persistent disability, or results in a congenital anomaly, it is categorized as a serious adverse event (SAE). The monitoring scope extends far beyond basic ADRs to encompass medication errors, counterfeit or substandard formulations, unexpected lack of therapeutic efficacy, drug abuse or off-label misuse, and hazardous drug-drug interactions.

The day-to-day workflow of pharmacovigilance follows a methodical operational cycle that starts with the collection of an Individual Case Safety Report (ICSR). A valid report requires four minimum elements: an identifiable patient, an identifiable reporter, a suspected medicinal product, and an adverse event. Once captured, drug safety associates triage the report and translate free-text clinical symptoms into standardized regulatory language using the Medical Dictionary for Regulatory Activities (MedDRA). Next, safety scientists perform causality assessments using validated algorithms—such as the Naranjo scale or the WHO-UMC criteria—evaluating temporal sequences, dechallenge (symptom resolution upon drug cessation), rechallenge (symptom recurrence upon re-exposure), and alternative etiologies. Data is then aggregated into vast international surveillance systems, most notably VigiBase, maintained by the Uppsala Monitoring Centre (UMC) in Sweden, as well as regulatory databases like the US FDA's FAERS, the EMA's EudraVigilance, and India's PvPI.

When statistical analysis of pooled data reveals a disproportionate frequency of unexpected events, safety experts identify a "signal" requiring formal investigation. If the risk is confirmed, regulatory agencies intervene by updating product labels with black-box warnings, restricting indicated patient populations, issuing safety communications to clinicians, or, in severe instances, issuing a market withdrawal. As modern healthcare embraces artificial intelligence, natural language processing, and real-world evidence from electronic health records, pharmacovigilance continues to evolve. For students in pharmacy, medicine, and life sciences, it represents both a critical safeguard for patient welfare and an essential discipline ensuring that the therapeutic benefits of modern medicines consistently outweigh their risks. Fig. 1.

2. Reference

1. Foundational Textbooks and Standard Reference Works

1. Academic pharmacovigilance is anchored in several definitive textbooks that outline clinical, regulatory, and epidemiological principles:
2. Mann's Pharmacovigilance (3rd Edition)
3. Editors: Elizabeth B. Andrews & Nicholas Moore (Wiley-Blackwell, 2014).
4. Core Focus: Widely considered the standard academic handbook for drug safety professionals. It provides exhaustive coverage of epidemiological methods, spontaneous reporting system mechanics, risk evaluation and mitigation strategies (REMS), and the legal frameworks operating in both the European Union and the United States.
5. Stephens' Detection of New Adverse Drug Reactions (5th Edition)
6. Editors: John Talbot & Patrick Waller (John Wiley & Sons, 2004).
7. Core Focus: Details the clinical logic of signal detection, post-marketing surveillance, and the pharmacological taxonomy of adverse reactions (e.g., Rawlins-Thompson classification).
8. Textbook of Pharmacoepidemiology (3rd Edition)
9. Editors: Brian L. Strom, Stephen E. Kimmel, & Sean Hennessy (Wiley, 2021).
10. Core Focus: Delivers the quantitative and biostatistical backbone of post-marketing drug surveillance, covering cohort studies, case-control analyses, prescription-event monitoring, and big-data observational databases.
11. Pharmacovigilance: A Practical Approach
12. Author: Thao Doan (Springer, 2019).
13. Core Focus: Tailored for trainees and drug safety associates; dissects triage protocols, narrative writing, MedDRA coding, and aggregate reporting timelines.

2. Definitive World Health Organization (WHO) Documents and UMC Frameworks

1. The global architecture of drug safety operates under treaties, resolutions, and operational manuals developed by the WHO and the Uppsala Monitoring Centre (UMC):
2. Core Organizational Guidelines
3. World Health Organization (2002): The Importance of Pharmacovigilance: Safety Monitoring of Medicinal Products. Geneva: World Health Organization.
4. Relevance: Established the globally accepted, expanded definition of pharmacovigilance as "the science and

activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems."

5. World Health Organization (2004): Pharmacovigilance: Ensuring the Safe Use of Medicines. WHO Policy Perspectives on Medicines, No. 5. Geneva: WHO.
6. Relevance: Outlines the rationale for national drug safety policies, spontaneous reporting centers, and public risk communication.
7. World Health Organization (2006): Safety Monitoring of Medicinal Products: Guidelines for Setting Up and Running a Pharmacovigilance Centre. Uppsala: Uppsala Monitoring Centre.
8. Relevance: The standard operational blueprint for developing countries establishing national pharmacovigilance centers, detailing reporting forms, causality assessment committees, and data submission criteria.
9. Uppsala Monitoring Centre (UMC) Technical Standards
10. UMC Causality Assessment System: The Use of the WHO-UMC System for Standardised Case Causality Assessment. Uppsala Monitoring Centre.
11. Parameters: Categorizes causality into Certain, Probable/Likely, Possible, Unlikely, Conditional/Unclassified, and Unassessable/Unclassifiable based on temporal relationships, dechallenge, rechallenge, and medical plausibility.
12. VigiBase Technical Manuals: Operates the WHO global database of Individual Case Safety Reports (ICSRs), processing data from over 170 member countries using statistical algorithms like the Information Component (IC) based on the Bayesian Confidence Propagation Neural Network (BCPNN).

3. Seminal Peer-Reviewed Literature and Historical Milestones

1. Historical Catalysts and Public Health Disasters
2. The Thalidomide Tragedy and the Awakening of Safety Science:
3. McBride, W. G. (1961). "Thalidomide and Congenital Abnormalities." *The Lancet*, 278(7216), 1358.
4. Significance: First published clinical letter identifying severe phocomelia in infants whose mothers were administered thalidomide during early gestation.
5. Lenz, W. (1962). "Thalidomide and Congenital Abnormalities." *The Lancet*, 279(7219), 45.
6. Significance: Independent confirmation

from Germany documenting hundreds of limb malformation cases, forcing global regulatory reform.

7. Sjöström, H., & Nilsson, R. (1972). *Thalidomide and the Power of the Drug Companies*. Penguin Books.

8. Significance: Comprehensive account of the corporate and clinical negligence that triggered the 1962 Kefauver-Harris Drug Amendments in the US and the creation of the UK Committee on Safety of Drugs (Yellow Card Scheme).

9. The Elixir Sulfanilamide Disaster (1937):

10. Wax, P. M. (1995). "Elixirs, Diluents, and the Passage of the 1938 Federal Food, Drug, and Cosmetic Act." *Annals of Internal Medicine*, 122(6), 456–461.

11. Significance: Analyzes the pharmacological catastrophe caused by diethylene glycol formulation that killed over 100 individuals, leading directly to the pre-marketing safety mandate under the US FD&C Act of 1938.

12. Foundational Causality and Classification Papers

13. The Naranjo Algorithm:

14. Naranjo, C. A., Busto, U., Sellers, E. M., Sandor, P., Ruiz, I., Roberts, E. A., Janecek, E., Domecq, C., & Greenblatt, D. J. (1981). "A method for estimating the probability of adverse drug reactions." *Clinical Pharmacology & Therapeutics*, 30(2), 239–245.

15. Relevance: Introduced the 10-question standardized scoring algorithm widely cited in clinical medicine and case triage to assign objective probability scores (Definite: ≥ 9 , Probable: $5\text{--}8$, Possible: $1\text{--}4$, Doubtful: ≤ 0).

16. Classification of Adverse Drug Reactions (Rawlins-Thompson System):

17. Rawlins, M. D., & Thompson, J. W. (1977). "Pathogenesis of adverse drug reactions." In: *Textbook of Adverse Drug Reactions* (ed. Davies, D. M.), Oxford University Press.

18. Relevance: Established the fundamental Type A (Augmented / dose-dependent / predictable) versus Type B (Bizarre / idiosyncratic / non-dose-dependent) taxonomy, later expanded by Aronson and Ferner to include Types C (Chronic), D (Delayed), E (End of use), and F (Failure).

19. Edwards, I. R., & Aronson, J. K. (2000). "Adverse drug reactions: definitions, diagnosis, and management." *The Lancet*, 356(9237), 1255–1259.

20. Relevance: Critical paper clarifying the boundaries between side effects, adverse reactions, and toxicities.

4. International Council for Harmonisation (ICH) Guidelines

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) publishes the legally binding technical guidelines that standardize pharmacovigilance across the FDA (USA), EMA (Europe), PMDA (Japan), and other major regulatory bodies: