

## Pharmacovigilance and Adverse Drug Reactions: A Comprehensive Review of Global and Indian Perspectives

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### Abstract:

Pharmacovigilance (PV) has emerged as an essential component of healthcare systems, aimed at identifying, evaluating, and preventing risks associated with medicines. With the rising complexity of therapeutics and the increasing burden of adverse drug reactions (ADRs), PV ensures that the benefits of drugs outweigh potential harms. This review presents an overview of the historical development of pharmacovigilance, the significance of ADR monitoring, and the functioning of global and national PV systems, including the World Health Organization's International Drug Monitoring Programme (IDMP) and the Pharmacovigilance Programme of India (PvPI). The review further explores drug and disease classification systems, vaccine safety surveillance, methodologies for safety data generation, and the role of pharmacogenomics in predicting ADRs. Special focus is given to vulnerable populations such as children, pregnant women, and the elderly. Challenges of underreporting, the need for effective communication strategies, and the integration of digital tools and artificial intelligence are also discussed. By highlighting current practices and future directions, this paper emphasizes the importance of strengthening PV systems for global drug safety and patient well-being.

**Keywords:** Pharmacovigilance, Adverse Drug Reactions, Drug Safety, Vaccine Surveillance, Pharmacogenomics, PvPI.

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### Introduction

Pharmacovigilance (PV) refers to the science and activities related to the detection, assessment, understanding, and prevention of adverse drug reactions (ADRs) or any other drug-related problems. As the global pharmaceutical industry continues to expand, the need for effective monitoring systems has become more pressing. ADRs are a leading cause of morbidity, hospitalizations, and even mortality worldwide, contributing significantly to healthcare costs. For instance, studies estimate that ADRs rank among the top 10 causes of death in some countries.

While clinical trials remain vital for initial safety assessment, their limitations such as small sample sizes, controlled environments, and short durations—make them insufficient to detect all potential risks.

Therefore, robust post-marketing surveillance systems are indispensable. PV bridges this gap by ensuring that once drugs are introduced into real-world clinical practice, safety concerns are continuously monitored. This paper reviews the historical evolution of pharmacovigilance, global

and national monitoring frameworks, methodologies for ADR detection, and the integration of modern scientific approaches such as pharmacogenomics.

### Historical Development and Importance of Pharmacovigilance

The concept of pharmacovigilance gained prominence after the thalidomide disaster in the late 1950s, where thousands of children were born with congenital deformities due to the drug's use in pregnancy.

This tragedy highlighted the inadequacy of pre-market safety testing and led to global reforms in drug regulation. The World Health Organization (WHO) established the International Drug Monitoring Programme in 1968, marking the beginning of structured global PV. Other landmark events include the rofecoxib (Vioxx) withdrawal in 2004 due to cardiovascular risks, which emphasized the continued need for strong post-marketing surveillance systems.

The importance of PV lies in: protecting public health, enabling risk management, guiding clinical decision-making, and improving therapeutic outcomes.

### **Adverse Drug Reactions: Classification, Detection, and Management**

ADRs can be classified as Type A (dose-dependent, predictable) or Type B (unpredictable, often severe). Severity ranges from mild to life-threatening. Detection methods include spontaneous reporting and active surveillance. Causality assessment tools such as the WHO-UMC system and the Naranjo Algorithm help determine the likelihood of ADRs. Management involves discontinuation of the offending drug, symptomatic treatment, reporting, and patient education.

### **Global and National Pharmacovigilance Systems**

The WHO International Drug Monitoring Programme (IDMP) is coordinated by the Uppsala Monitoring Centre and collects ADR data through Vigibase. The Pharmacovigilance Programme of India (PvPI), launched in 2010, operates under CDSCO and IPC, with over 400 Adverse Drug Reaction Monitoring Centres collecting data and issuing regulatory alerts.

**Drug and Disease Classification in Pharmacovigilance:** Drug classification can be anatomical, therapeutic, or chemical. The International Classification of Diseases (ICD) standardizes disease reporting. WHO tools like the Daily Defined Dose (DDD) and International Non-proprietary Names (INN) ensure consistency in prescribing and reporting. The WHO Drug Dictionary and MedDRA terminology support accurate ADR reporting.

**Vaccine Safety Surveillance:** Vaccine safety is monitored through adverse events following immunization (AEFI). Passive surveillance (e.g., VAERS, India's AEFI program) and active methods (sentinel sites, registries) are employed. WHO's Global Vaccine Safety Initiative strengthens global monitoring. Challenges include underreporting and distinguishing coincidental from true ADRs.

### **Safety Data Generation and ICH Guidelines**

Safety data are generated across preclinical, clinical, and post-marketing phases. Preclinical studies focus on toxicology and pharmacokinetics. Clinical trials (Phase I–III) assess safety and efficacy. Post-marketing surveillance detects rare

ADRs. ICH guidelines harmonize practices globally. Tools include Individual Case Safety Reports (ICSRs), Periodic Safety Update Reports (PSURs), and Risk Management Plans (RMPs).

### **Pharmacogenomics and Special Populations**

Pharmacogenomics studies genetic variations that affect drug response, particularly involving CYP450 enzymes. Special populations like children, pregnant women, and the elderly are more vulnerable to ADRs due to physiological differences. PV in these groups requires special focus.

**Communication and Risk Management in Pharmacovigilance:** Effective communication between regulators, healthcare providers, patients, and the media is critical. Risk management includes label changes, usage restrictions, and recalls. Patient engagement and self-reporting through apps are gaining importance. Crisis communication is vital during drug withdrawals or vaccine controversies.

### **Discussion**

Despite progress, underreporting of ADRs remains a major challenge, with estimates suggesting only 6–10% of ADRs are reported globally. Emerging technologies like artificial intelligence and big data analytics can enhance ADR detection. In India, PvPI has advanced significantly, but rural integration and greater patient involvement are still needed.

### **Conclusion**

Pharmacovigilance is essential for ensuring drug safety and protecting public health. Its evolution highlights its critical role in healthcare. Future directions include integrating AI, genomics, and global collaboration to strengthen drug safety systems.

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