



Cover Page



A REVIEW ON PHARMACOVIGILANCE

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Abstract

Pharmacovigilance is an essential component of modern healthcare systems that focuses on the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. The increasing complexity of therapeutic interventions, globalization of pharmaceutical markets, and growing use of traditional and complementary medicines have expanded the importance of pharmacovigilance worldwide. Adverse drug reactions (ADRs) contribute significantly to morbidity, mortality, prolonged hospitalization, and economic burden. Effective pharmacovigilance systems ensure patient safety, improve therapeutic outcomes, and strengthen public confidence in healthcare services. This review discusses the historical evolution, objectives, scope, methods, regulatory framework, reporting systems, challenges, and future perspectives of pharmacovigilance. Special emphasis is given to pharmacovigilance in India and the role of healthcare professionals in ADR monitoring and reporting. The article also highlights the integration of artificial intelligence, digital technologies, and real-world evidence in strengthening pharmacovigilance activities.

Keywords: Pharmacovigilance, Adverse Drug Reaction, Drug Safety, Patient Safety, ADR Reporting, PvPI

Introduction

Medicinal products have transformed healthcare by reducing disease burden and improving quality of life. However, no medicine is completely free from adverse effects. Adverse drug reactions remain one of the major causes of morbidity and mortality globally. Drug safety monitoring has therefore become an integral part of healthcare systems. Pharmacovigilance plays a significant role in identifying previously unrecognized adverse effects, assessing risk-benefit profiles of medicines, and promoting safe and rational use of drugs.

The World Health Organization (WHO) defines pharmacovigilance as “the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.” Pharmacovigilance activities extend beyond conventional medicines and include vaccines, biological products, herbal medicines, traditional systems of medicine, medical devices, and blood products.

The thalidomide tragedy of the 1960s marked a turning point in drug safety monitoring and led to the establishment of structured pharmacovigilance systems globally. Since then, many countries have developed national pharmacovigilance programs to monitor medicine safety and protect public health.

Historical Background of Pharmacovigilance

The history of pharmacovigilance dates back several decades. Initially, drug safety monitoring was limited due to inadequate regulatory systems and lack of awareness regarding adverse drug reactions.

Early Developments

- In 1848, one of the earliest documented ADR-related deaths occurred due to chloroform anaesthesia.
- Sulphanilamide elixir disaster in 1937 in the United States caused more than 100 deaths because of diethylene glycol toxicity.



Cover Page



- The thalidomide disaster during the late 1950s and early 1960s resulted in congenital abnormalities in thousands of newborns.

These incidents highlighted the need for strict drug regulation and systematic monitoring of medicine safety.

WHO Programme for International Drug Monitoring

In 1968, the WHO established the Programme for International Drug Monitoring to facilitate international collaboration in monitoring ADRs. The Uppsala Monitoring Centre (UMC) in Sweden currently manages the global ADR database known as VigiBase.

Objectives of Pharmacovigilance

The primary objectives of pharmacovigilance include:

1. Detection of previously unknown adverse drug reactions.
2. Identification of risk factors associated with ADRs.
3. Assessment of benefit-risk balance of medicines.
4. Promotion of rational and safe use of medicines.
5. Improvement of patient care and patient safety.
6. Prevention of medication-related harm.
7. Generation of evidence-based information for regulatory decision-making.
8. Enhancement of public confidence in healthcare systems.

Scope of Pharmacovigilance

The scope of pharmacovigilance has expanded significantly over the years. It now includes:

- Adverse drug reactions.
- Medication errors.
- Drug interactions.
- Drug overdose and poisoning.
- Lack of therapeutic efficacy.
- Vaccine safety monitoring.
- Herbal and traditional medicine safety.
- Biological products and biosimilars.
- Medical devices and diagnostic agents.
- Drug abuse and misuse.



Cover Page



Pharmacovigilance also supports public health programs by monitoring the safety of medicines used in mass treatment campaigns and immunization programs.

Adverse Drug Reactions

Definition

An adverse drug reaction is a harmful and unintended response to a medicine occurring at doses normally used for prophylaxis, diagnosis, or treatment.

Classification of ADRs

ADR classification helps in understanding mechanisms and improving prevention strategies.

Type A (Augmented)

- Dose dependent.
- Predictable from pharmacological action.
- Common and less severe.
- Example: Hypoglycemia caused by insulin.

Type B (Bizarre)

- Unpredictable.
- Not dose dependent.
- Often immunological or idiosyncratic.
- Example: Penicillin-induced anaphylaxis.

Type C (Chronic)

- Related to long-term use.
- Example: Corticosteroid-induced osteoporosis.

Type D (Delayed)

- Appears after prolonged exposure.
- Example: Carcinogenicity.

Type E (End of Use)

- Associated with withdrawal.
- Example: Opioid withdrawal syndrome.



Cover Page



Type F (Failure)

- Therapeutic failure.
- Example: Antibiotic resistance.

Methods of Pharmacovigilance

Various methods are used to monitor medicine safety.

Passive Surveillance

Spontaneous Reporting

Spontaneous reporting systems are the foundation of pharmacovigilance. Healthcare professionals and consumers voluntarily report suspected ADRs to national centers.

Advantages:

- Simple and cost-effective.
- Useful for detecting rare ADRs.

Limitations:

- Underreporting.
- Incomplete information.
- Reporting bias.

Active Surveillance

Active surveillance involves proactive monitoring of drug safety.

Sentinel Sites

Selected healthcare centers collect detailed ADR data.

Drug Event Monitoring

Patients receiving specific medicines are followed systematically.

Registries

Disease or drug-specific registries help identify long-term safety outcomes.

Comparative Observational Studies

- Case-control studies.
- Cohort studies.
- Cross-sectional studies.



Cover Page



These studies are valuable for evaluating associations between drugs and adverse events.

Clinical Trials

Clinical trials contribute to pre-marketing safety evaluation. However, rare ADRs may not be identified because of limited sample size and duration.

Pharmacovigilance Programme of India (PvPI)

India launched the Pharmacovigilance Programme of India (PvPI) in 2010 under the Ministry of Health and Family Welfare.

Objectives of PvPI

- Monitor ADRs in the Indian population.
- Promote patient safety.
- Create awareness among healthcare professionals.
- Generate evidence for regulatory interventions.

The Indian Pharmacopoeia Commission (IPC) serves as the National Coordination Centre for PvPI.

ADR Monitoring Centres

ADR Monitoring Centres (AMCs) are established in medical colleges and hospitals across India to collect and report ADR data.

Reporting Process

Healthcare professionals including doctors, pharmacists, nurses, dentists, and consumers can report suspected ADRs through:

- ADR reporting forms.
- Toll-free helpline.
- Mobile applications.
- Online reporting systems.

Role of Healthcare Professionals

Healthcare professionals play a central role in pharmacovigilance.

Physicians

- Identification and reporting of ADRs.
- Rational prescribing.
- Monitoring drug therapy.



Cover Page



Pharmacists

- Detection of medication errors.
- Patient counseling.
- ADR documentation.
- Drug information services.

Nurses

- Observation of patient responses.
- Early identification of ADRs.
- Patient education.

Dentists and Other Professionals

Dental practitioners and allied healthcare professionals also contribute to reporting drug-related adverse events.

Pharmacovigilance in Herbal and Traditional Medicines

The use of herbal medicines and traditional systems such as Ayurveda, Siddha, Unani, and Homeopathy has increased globally. Although these medicines are generally perceived as safe, adverse reactions and herb-drug interactions may occur.

Challenges in herbal pharmacovigilance include:

- Lack of standardization.
- Variability in formulations.
- Adulteration and contamination.
- Inadequate documentation.

India has initiated pharmacovigilance programs for AYUSH systems to ensure the safety of traditional medicines.

Signal Detection in Pharmacovigilance

A signal is information suggesting a possible causal relationship between a drug and an adverse event that requires further investigation.

Sources of Signals

- Spontaneous ADR reports.
- Clinical studies.
- Scientific literature.
- Electronic health records.



Cover Page



- Social media monitoring.

Signal detection involves statistical analysis and expert evaluation to determine clinical significance.

Regulatory Aspects of Pharmacovigilance

Regulatory authorities establish guidelines for drug safety monitoring.

International Regulatory Agencies

- World Health Organization (WHO).
- United States Food and Drug Administration (USFDA).
- European Medicines Agency (EMA).
- Medicines and Healthcare products Regulatory Agency (MHRA).

Key Regulatory Functions

- Post-marketing surveillance.
- Risk management plans.
- Labeling changes.
- Drug recalls.
- Safety alerts.

Regulatory decisions are based on continuous evaluation of benefit-risk balance.

Challenges in Pharmacovigilance

Despite significant progress, several challenges affect pharmacovigilance systems.

Underreporting of ADRs

Many ADRs remain unreported due to lack of awareness, fear of legal consequences, or uncertainty regarding causality.

Inadequate Training

Healthcare professionals may lack proper training in ADR reporting procedures.

Data Quality Issues

Incomplete and inaccurate reports reduce the effectiveness of pharmacovigilance systems.

Polypharmacy

Multiple drug use complicates identification of causative agents.



Cover Page



Herbal Medicine Monitoring

Insufficient scientific evidence and poor regulation create challenges in monitoring traditional medicines.

Resource Constraints

Limited infrastructure and financial resources hinder pharmacovigilance activities in developing countries.

Emerging Trends in Pharmacovigilance

Modern pharmacovigilance is rapidly evolving with technological advancements.

Artificial Intelligence and Machine Learning

Artificial intelligence (AI) helps in:

- Automated signal detection.
- Data mining.
- Pattern recognition.
- Predictive safety analysis.

Machine learning algorithms can process large datasets efficiently and improve detection of rare ADRs.

Big Data and Real-World Evidence

Electronic health records, insurance databases, and patient registries provide real-world evidence for evaluating medicine safety.

Mobile Health Applications

Mobile apps facilitate rapid ADR reporting and patient engagement.

Pharmacogenomics

Pharmacogenomics identifies genetic factors influencing drug response and susceptibility to ADRs.

Social Media Surveillance

Online platforms and social media provide additional information regarding patient experiences and medicine safety concerns.

Importance of Pharmacovigilance

Pharmacovigilance offers several benefits:

- Enhances patient safety.
- Supports rational drug use.
- Reduces healthcare costs.



Cover Page



- Improves therapeutic outcomes.
- Strengthens regulatory decision-making.
- Promotes public confidence in medicines.
- Identifies rare and delayed ADRs.

Effective pharmacovigilance systems contribute significantly to quality healthcare delivery.

Future Perspectives

Future pharmacovigilance systems are expected to become more patient-centered, technology-driven, and globally integrated. Integration of artificial intelligence, blockchain technology, and real-time data analytics may improve early detection of safety signals. Increased collaboration among healthcare professionals, pharmaceutical industries, regulatory agencies, and patients is essential for strengthening drug safety systems.

Pharmacovigilance in traditional medicine systems should also receive greater attention because of increasing global utilization of herbal products. Educational programs and awareness campaigns can improve ADR reporting rates and ensure safer use of medicines.

Conclusion

Pharmacovigilance is a vital discipline that safeguards public health by ensuring the safe use of medicines. Continuous monitoring of adverse drug reactions and drug-related problems helps identify potential risks and supports evidence-based regulatory decisions. The increasing burden of ADRs emphasizes the need for robust pharmacovigilance systems at national and international levels. Active participation of healthcare professionals, patients, regulatory authorities, and pharmaceutical industries is essential for successful pharmacovigilance programs. Technological innovations such as artificial intelligence, big data analytics, and pharmacogenomics are expected to transform the future of pharmacovigilance and improve patient safety worldwide.

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Cover Page



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