ISSN: 2767-8245

Available online on http://www.ijdcs.com/

International Journal of Dental and Clinical Studies 2026; 7(3) 01-4

Pharmacovigilance: An Essential Approach to Medicine Safety, ADR Reporting and Risk Management

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Conflict of interest: No conflict of interest

Abstract:
Pharmacovigilance is an important branch of pharmaceutical and medical science concerned with the continuous monitoring of the safety and proper use of medicines. It includes the detection, collection, monitoring, assessment, understanding and prevention of adverse drug reactions (ADRs) and other medicine-related problems. Clinical trials cannot identify every possible adverse effect because medicines are studied in limited populations and for limited periods. Post-marketing monitoring is therefore essential for identifying rare, unexpected and long-term safety problems. This review summarizes the major concepts of pharmacovigilance, ADR classification and reporting, spontaneous reporting systems, documentation, causality assessment, signal detection, risk management and the role of pharmacists. The review also discusses the importance of patient safety, medication-error monitoring and the Pharmacovigilance Programme of India (PvPI). Effective and timely ADR reporting, accurate documentation, continuous safety monitoring and appropriate risk-minimization measures are essential for maintaining a favorable benefit–risk balance and promoting the safe and rational use of medicines.
Keywords: Pharmacovigilance; Adverse Drug Reactions; ADR Reporting; Signal Detection; Risk Management; Risk Management Plan; Patient Safety; Pharmacist; PvPI.

Introduction

Pharmacovigilance (PV) focuses on the safety and proper use of medicines. It involves continuous monitoring of medicines to identify and evaluate adverse effects and other medicine-related problems. Safety information may be obtained from healthcare professionals, patients, clinical studies, spontaneous ADR reports, medical literature, electronic health records and other sources.

Pharmacovigilance supports safer prescribing, better patient care and prevention of avoidable harm.

The need for pharmacovigilance became particularly clear after the thalidomide tragedy, in which use of the medicine was associated with severe birth defects. Subsequent development of formal reporting and monitoring systems strengthened medicine-safety surveillance. Modern pharmacovigilance uses databases, data analysis, signal detection and international collaboration to monitor medicines throughout their life cycle.

Importance of Pharmacovigilance: Medicines may produce unwanted or unexpected effects in some patients. Rare reactions, delayed effects, interactions and problems occurring in special populations may become apparent only after widespread use. Pharmacovigilance helps identify previously unknown safety problems, evaluate benefit–risk balance, improve prescribing practices and reduce medicine-related harm.

Its importance extends to medicines, vaccines, biological products, herbal medicines, medical devices and other healthcare products. Continuous monitoring after marketing is particularly important because real-world medicine use involves diverse patients, health conditions, lifestyles, diets and concomitant medicines.

Objectives of Pharmacovigilance

- Detection and monitoring of adverse drug reactions.
- Collection and systematic analysis of medicine-safety information.
- Evaluation of the benefits and risks of medicines.
- Early identification of new or unexpected safety signals.
- Risk identification, assessment and minimization.
- Prevention of avoidable medicine-related harm.
- Promotion of safe and rational use of medicines.
- Protection of patients and improvement of public health.

Adverse Drug Reactions (ADRs)

An adverse drug reaction is a harmful or unwanted response associated with the use of a medicine. ADRs may be known and documented or may be previously unrecognized. Proper identification, documentation and assessment of ADRs are important components of pharmacovigilance.

ADRs may be classified using the commonly described Type A–F framework:

Type A (augmented) reactions are generally predictable and dose-dependent;

Type B (bizarre) reactions are unpredictable;

Type C (chronic) reactions are associated with long-term use;

Type D (delayed) reactions appear after a considerable period;

Type E (end-of-use) reactions occur after withdrawal; and

Type F (failure of therapy) occurs when expected therapeutic effects are not achieved.

ADR Reporting

ADR reporting is a key activity of pharmacovigilance. Doctors, pharmacists, nurses and other healthcare professionals can report suspected ADRs encountered during routine practice.

Reports should contain relevant patient information, suspected medicine, dose, dosage form, and route, and treatment duration, description of the reaction, onset, concomitant medicines and outcome.

Spontaneous Reporting Systems (SRS) provide an important mechanism for collecting suspected ADR information.

Reports are evaluated to identify possible safety problems and may generate signals requiring further investigation. Serious or clinically important reactions should be documented and reported promptly through the appropriate pharmacovigilance system.

Standard Operating Procedure (SOP) for ADR Reporting

1. Identification of the suspected ADR.
2. Collection of relevant patient information while maintaining confidentiality.
3. Collection of complete information about the suspected medicine and concomitant medicines.
4. Documentation of the reaction, onset, severity, treatment and outcome.
5. Assessment of seriousness.
6. Causality assessment, considering the time relationship, alternative causes, dechallenge, re-challenge and concomitant medicines.
7. Completion of the appropriate ADR reporting form.
8. Submission to the appropriate pharmacovigilance centre.
9. Follow-up of the case when additional information is required.
10. Confidential maintenance of records for further evaluation and signal detection.

Signal Detection and Management

A safety signal is information suggesting a possible new relationship between a medicine and an adverse event that requires further investigation. Signals may arise from individual case safety reports, spontaneous reporting systems, clinical trials, medical and scientific literature, electronic health records and pharmacovigilance databases.

The general signal-management process can be represented as: Data Collection → Signal Detection → Signal Validation → Assessment → Recommendation/Action → Monitoring. Signal management helps determine whether a safety concern requires further investigation, additional monitoring or appropriate safety action.

Risk Management in Pharmacovigilance

Risk management is the systematic process of identifying, assessing, monitoring and minimizing risks associated with medicines. The purpose is not to eliminate every possible risk, but to maintain a favorable benefit–risk balance by identifying important risks and applying suitable risk-minimization measures.

Risk assessment considers factors such as severity, frequency, seriousness, preventability and the population affected. Risk-minimization measures may include appropriate dosage recommendations, contraindications, warnings and precautions, patient counselling, healthcare-professional education, regular monitoring and restrictions of medicine use in specific patient groups when required.

Risk Management Plan (RMP)

A Risk Management Plan is a structured document describing known and potential risks of a medicine and the activities used to monitor and control those risks. Important elements include the safety profile, important identified risks, important potential risks, missing information, pharmacovigilance activities, risk-minimization measures and monitoring of the effectiveness of those measures.

Pharmacovigilance Data Sources

- Spontaneous ADR reports.
- Clinical trials.
- Post-marketing surveillance.
- Medical and scientific literature.
- Patient reports.
- Healthcare-professional reports.

- Electronic health records and patient registries.
- Epidemiological and pharmacoepidemiological studies.

Role of the Pharmacovigilance Pharmacist

Pharmacists can contribute to medicine safety through identification, reporting and documentation of suspected ADRs.

Their role may also include case follow-up, patient counselling, medication-error monitoring, review of medicine information and communication of safety concerns to healthcare teams. Active participation of pharmacists supports safe and rational medicine use and strengthens pharmacovigilance practice.

Medication Errors and Patient Safety

Medication errors may involve the wrong drug, wrong dose, wrong route, incorrect frequency or drug interactions.

Understanding and documenting such errors is important because many are potentially preventable through appropriate prescribing, dispensing, administration and monitoring. Pharmacovigilance activities contribute to patient safety by identifying medicine-related problems and supporting corrective and preventive measures.

Pharmacovigilance Programme of India (PvPI):

The Pharmacovigilance Programme of India (PvPI) plays an important role in strengthening medicine-safety monitoring in India. Healthcare professionals, including pharmacists, doctors and nurses, can contribute by identifying suspected ADRs, collecting relevant patient and medicine information, documenting events accurately and reporting them through the appropriate pharmacovigilance system.

Example: Pharmacovigilance of Clobetasol Propionate Ointment:

Clobetasol propionate is a topical corticosteroid available as an ointment and used for corticosteroid-responsive inflammatory skin conditions. Safety monitoring is important because prolonged or inappropriate use of potent topical corticosteroids may be associated with local or systemic adverse effects.

- Burning sensation
- Itching
- Skin thinning (atrophy)
- Changes in skin pigmentation
- Stretch marks (striae)
- Potential systemic corticosteroid effects with excessive or prolonged use

Risk-minimization measures include using the ointment only as directed, avoiding unnecessary prolonged use, and providing appropriate patient counselling, monitoring during prolonged treatment and reporting suspected adverse reactions through the appropriate system.

Challenges in Pharmacovigilance

- Under-reporting of suspected ADRs.
- Incomplete or inaccurate information in reports.
- Limited awareness of ADR reporting among patients and healthcare professionals.
- Difficulty in distinguishing medicine-related events from underlying disease.
- Need for timely follow-up and complete case information.
- Growing volume and complexity of safety data requiring effective analysis.

Future Perspectives

Digital and electronic reporting systems can make ADR reporting easier, faster and more accessible. Continued use of structured safety databases, data analysis and signal-detection approaches can support earlier identification of potential safety concerns. Increased education of healthcare professionals and patients, stronger communication and continuous benefit–risk evaluation can further strengthen pharmacovigilance.

Conclusion

Pharmacovigilance is an essential and continuous process for maintaining the safety of medicines and protecting patients. ADR reporting, accurate documentation, causality assessment, signal detection, risk assessment and risk minimization work together to identify and control medicine-related risks.

Since clinical trials cannot reveal every possible adverse effect, post-marketing monitoring remains necessary. Active participation of pharmacists, doctors, nurses, patients, pharmaceutical organizations and regulatory systems is important for improving medicine safety. Strong pharmacovigilance ultimately supports safer and more rational use of medicines and helps maintain a favorable benefit–risk balance.

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