

Pharmacovigilance

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- Pharmacovigilance (PV) is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.
- The term comes from two words:
 - **"Pharmaco"** – relating to drugs or medicines.
 - **"Vigilance"** – to be watchful or alert.
- It is a discipline that ensures medicines are used safely and that any risks associated with drug use are identified and managed appropriately.

Aim of Pharmacovigilance

The main aims of pharmacovigilance include:

- To improve patient safety by identifying risks associated with medicinal products.
- To enhance public health through timely detection and communication of safety issues.
- To ensure the benefit-risk balance of a drug remains favorable after its release.
- To support informed decision-making in clinical practice and public health.
- To prevent harm caused by adverse drug reactions (ADRs) or drug interactions.

Scope of Pharmacovigilance

The scope of pharmacovigilance has expanded over time and now includes:

- **Adverse Drug Reactions (ADRs)** – unwanted or harmful reactions experienced after the administration of a drug.
- **Medication errors** – mistakes in prescribing, dispensing, or administering medicines.
- **Drug interactions** – effects caused when one drug affects the activity of another.
- **Drug misuse and abuse** – inappropriate use of medication, intentionally or unintentionally.
- **Counterfeit drugs** – fake medicines that may be ineffective or harmful.
- **Lack of efficacy** – when a drug does not produce the intended therapeutic effect.
- **Monitoring drug safety in special populations** – such as children, pregnant women, elderly, and those with comorbidities.

Overview of Pharmacovigilance:

- Pharmacovigilance is a critical part of the healthcare and pharmaceutical industries. It involves a systematic approach to ensuring drug safety throughout the lifecycle of a medicinal product.
- Pharmacovigilance is a core component of drug regulation and healthcare systems worldwide. It plays a vital role in:
 - **Early detection of safety signals:** Identifying potential risks before they become widespread.
 - **Risk-benefit evaluation:** Determining whether a drug's benefits outweigh its risks.
 - **Regulatory decisions:** Such as label changes, restrictions in usage, or product withdrawals.
 - **Communication:** Informing healthcare professionals and the public about safe use of medicines.

Key Elements of Pharmacovigilance:

A. Data Collection

- Reports are collected from multiple sources including:
 - Healthcare providers
 - Patients
 - Clinical trials
 - Literature
 - Social media and mobile apps (emerging sources)

B. Signal Detection

- A signal is a new safety finding or a change in the frequency or severity of a known reaction.
- Signal detection uses statistical tools and clinical judgment to identify patterns from collected data.

C. Risk Assessment

- Collected information is evaluated to understand:
 - Severity
 - Frequency
 - Impact on different populations
 - Causality (whether the drug caused the reaction)

D. Risk Management

- Regulatory agencies and pharmaceutical companies develop risk management plans (RMPs) to:

- Minimize risks
- Educating healthcare professionals and patients
- Monitor ongoing safety

E. Regulatory Action

- Based on findings, authorities may:
 - Update prescribing information
 - Issue safety alerts
 - Restrict use
 - Withdraw the drug from the market

Regulatory Bodies Involved in Pharmacovigilance

- **WHO Uppsala Monitoring Centre (UMC)** – international center for PV.
- **US FDA** – Food and Drug Administration (USA).
- **EMA** – European Medicines Agency (EU).
- **MHRA** – Medicines and Healthcare products Regulatory Agency (UK).
- **CDSCO** – Central Drugs Standard Control Organization (India).
- **TGA** – Therapeutic Goods Administration (Australia).
- Supports development of safer pharmaceuticals.

Importance of Pharmacovigilance:

- Protects patients from avoidable harm.
- Informs healthcare decisions by ensuring up-to-date safety data is available.
- Supports regulatory actions like drug recalls, safety alerts, or restrictions.
- Contributes to the evolution of safer drug therapies over time.

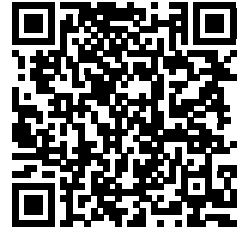


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