

Introduction To Pharmacovigilance

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Definition:

- Pharmacovigilance (PV) is defined by the World Health Organization (WHO) as:
 - "The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems."

Introduction to Pharmacovigilance



Key Objectives:

- Ensure patient safety by identifying and minimizing risks associated with drug use.
- Detect adverse drug reactions (ADRs) that may not have been evident in clinical trials.
- Enhance understanding of a drug's risk-benefit profile over time.
- Promote rational use of medications.

Why Is Pharmacovigilance Important?

- Clinical trials are limited in size and duration; not all side effects can be identified before a drug is approved.
- Real-world usage may reveal rare or long-term adverse effects.
- Continuous monitoring helps in updating drug information, issuing warnings, or even withdrawing harmful drugs from the market.

Core Activities:

- Spontaneous reporting of ADRs by healthcare professionals and patients.
- Signal detection and data analysis to identify new risks.
- Risk management plans (RMPs) and safety monitoring protocols.
- Communication of safety information to healthcare professionals and the public.

Key Organizations:

- **WHO:** World Health Organization coordinates international pharmacovigilance efforts.
- **EMA:** European Medicines Agency.
- **FDA:** U.S. Food and Drug Administration.
- **Uppsala Monitoring Centre (UMC):** Global center for pharmacovigilance established by WHO.

History and Development of Pharmacovigilance

- The development of pharmacovigilance has been shaped by historical events that highlighted the need for systematic monitoring of drug safety.

Early History: Pre-1960s

- **Pre-modern era:** There was no formal system to monitor drug safety. Adverse effects were often reported anecdotally or remained unnoticed.
- **1906 (USA):** The **Pure Food and Drug Act** laid the groundwork for drug regulation in the United States.
- **1937 – Sulfanilamide Disaster (USA):**
 - Over 100 people died due to a toxic solvent (diethylene glycol) in a sulfa drug preparation.
 - Resulted in the Federal Food, Drug, and Cosmetic Act (1938), which required safety testing before marketing.

Thalidomide Tragedy – 1960s

- Thalidomide was marketed as a sedative and treatment for morning sickness in pregnant women.
- Led to thousands of birth defects (phocomelia) in over 40 countries.
- Prompted major reforms:
 - Stricter drug approval processes.
 - Initiation of post-marketing surveillance systems.

International Coordination – 1968 Onwards

- **1968:** WHO launched the Programme for International Drug Monitoring.
- **Uppsala Monitoring Centre (Sweden):** Became the global hub for safety data.
- National systems like the UK's **Yellow Card Scheme** were established.

Modern Era of Pharmacovigilance (1990s–Present)

- **1995:** European Medicines Agency (EMA) formed to unify EU pharmacovigilance.
- **2000s:** Introduction of Risk Management Plans (RMPs) and tighter regulations.
- **2004:** Launch of EudraVigilance – EU's electronic ADR reporting system.

- **2012:** Major EU legislation reform to boost transparency and patient involvement.
- **Recent Trends:**
 - Global collaboration (WHO, EMA, FDA, etc.).
 - Use of AI, real-world data (RWD), and electronic health records (EHRs) for signal detection.

Importance of Safety Monitoring of Medicines

- The primary aim of pharmacovigilance is to ensure patient safety and rational use of medicines.

Here's why safety monitoring is crucial:

1. Medicines Are Not Completely Risk-Free

- Even after rigorous clinical trials, medicines may have unrecognized side effects, particularly rare or long-term effects.
- Some adverse effects may only become apparent when a medicine is used by large, diverse populations.

2. Clinical Trials Have Limitations

- Limited number of participants.
- Short study durations.
- Controlled conditions.
- Exclude certain populations (children, elderly, pregnant women).
 - Hence, post-marketing surveillance becomes essential.

3. Role in Post-Marketing Surveillance

- Also known as Phase IV studies.
- Pharmacovigilance collects real-world data on medicine use, identifying new adverse drug reactions (ADRs).
- Helps in evaluating and updating the benefit-risk ratio of a drug over time.

4. Regulatory and Public Health Significance

- Helps regulatory authorities (e.g., FDA, EMA, CDSCO) to:
 - Add warnings and precautions.
 - Restrict use or contraindicate in specific populations.
 - Suspend or withdraw drugs from the market.

5. Improves Patient Outcomes



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