

Pharmacovigilance

Introduction to Pharmacovigilance

Definition of Pharmacovigilance:

- Pharmacovigilance 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 problem."
- This includes the ongoing monitoring of medications after they are released to the market (post-marketing surveillance) to ensure their continued safety and efficacy in real-world use.
- It is a critical component of clinical pharmacy because pharmacists are among the healthcare professionals closest to the point of medication use.

Scope of Pharmacovigilance:

The scope of pharmacovigilance has evolved significantly over the years and now includes the following areas:

A. Adverse Drug Reactions (ADRs):

- Monitoring and managing side effects and harmful reactions caused by drugs in normal clinical use.

B. Medication Errors:

- Includes prescribing, dispensing, administration errors, and monitoring errors.

C. Drug Interactions:

- Identification of harmful interactions between multiple drugs or between drugs and foods.

D. Counterfeit and Substandard Medicines:

- Detection and control of fake or low-quality medications.

E. Lack of Efficacy Reports:

- Documentation of drugs that fail to produce their intended therapeutic effect.

F. Off-label Drug Use Monitoring:

- Surveillance of drug use outside the conditions approved by regulatory agencies (e.g., different dosages, routes, indications).

G. Drug Abuse and Misuse:

- Monitoring the intentional or unintentional misuse of medications, especially controlled substances.

H. Herbal and Traditional Medicines:

- Includes vigilance for products not strictly regulated by standard pharmaceutical frameworks.

I. Pharmacogenetics and Pharmacogenomics:

- Understanding genetic factors that influence drug response and side effects.

J. Product Quality Defects:

- Identification and monitoring of issues related to formulation, stability, packaging, etc.

Aims/Objectives of Pharmacovigilance:

1. Improve Patient Care:

- By ensuring drug safety and minimizing risks to patients.

2. Enhance Public Health:

- Reducing the burden of drug-related morbidity and mortality.

3. Promote Rational Use of Medicines:

- Providing feedback that can be used to inform better prescribing and medication practices.

4. Encourage Safe Use of Medicines:

- Educating healthcare professionals and patients about known risks and safe practices.

5. Support Regulatory Decision-Making:

- Offering data that help in drug approval, withdrawal, or changes to labeling and usage.

6. Promote Understanding of Risk–Benefit Balance:

- Helping stakeholders (regulators, healthcare professionals, and patients) make informed decisions about therapies.

Adverse Drug Reactions (ADRs)

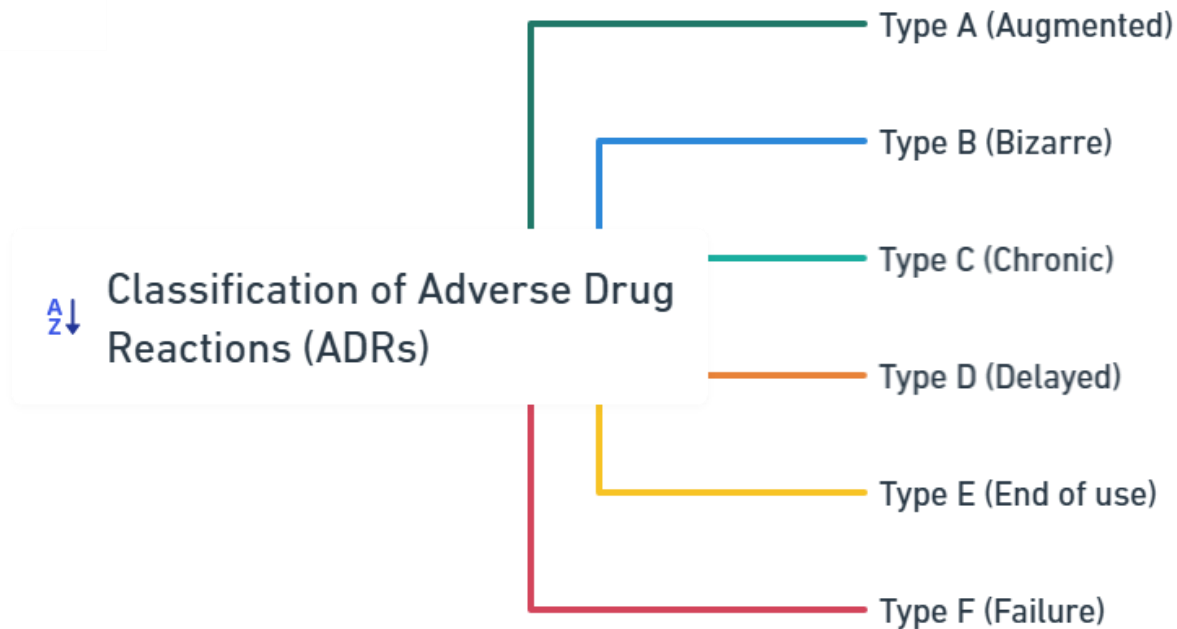
Definition of ADR:

- According to the WHO, an Adverse Drug Reaction (ADR) is:
 - “A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function.”
- This excludes poisoning and drug overdose, although those are still monitored under pharmacovigilance frameworks.

Classification of ADRs:

- ADRs can be classified based on various systems.

- The most used classification is the **Rawlins and Thompson Classification**, which includes:



1. Type A (Augmented):

- **Definition:** Predictable from the known pharmacology of the drug.
- **Dose-dependent.**
- **More common.**
- **Usually preventable or manageable.**
- **Examples:** Hypoglycemia with insulin, bleeding with warfarin.

2. Type B (Bizarre):

- **Definition:** Not predictable from the drug's pharmacology.
- **Not dose-dependent.**
- **Uncommon but potentially severe.**
- **Examples:** Anaphylaxis with penicillin, Stevens-Johnson syndrome with carbamazepine.

3. Type C (Chronic):

- **Definition:** Related to long-term therapy.
- **Examples:** Tardive dyskinesia with antipsychotics, adrenal suppression with corticosteroids.

4. Type D (Delayed):

- **Definition:** Appears after a long time following exposure.
- **Examples:** Carcinogenesis, teratogenesis (thalidomide-induced birth defects).

5. Type E (End of use):

- **Definition:** Associated with withdrawal of the drug.

- **Examples:** Withdrawal seizures after stopping benzodiazepines.

6. Type F (Failure):

- **Definition:** Therapeutic failure, possibly due to drug interaction, resistance, or poor quality.
- **Examples:** Antibiotic failure due to resistance.

Mechanisms of ADRs:

A. Pharmacological Mechanism:

- Excessive pharmacological effect.
- Example: Bradycardia with beta-blockers.

B. Pathological Mechanism:

- Tissue damage caused by the drug.
- Example: Hepatotoxicity with paracetamol overdose.

C. Immunological Mechanism (Drug allergy):

- Drug acts as antigen or hapten.
- Types I–IV hypersensitivity reactions.
- Example: Penicillin-induced anaphylaxis.

D. Genetic Mechanisms:

- Genetic polymorphisms affecting drug metabolism or transport.
- Example: G6PD deficiency leading to hemolysis with primaquine.

E. Drug Interactions:

- Pharmacokinetic or pharmacodynamic interactions leading to increased toxicity or therapeutic failure.

Predisposing Factors for ADRs:

1. Patient-related Factors:

- Age (very young or old).
- Gender (e.g., women more prone to certain reactions).
- Genetic factors.
- Liver or kidney dysfunction.
- Allergy history.
- Polypharmacy.
- Alcohol or substance abuse.

2. Drug-related Factors:

- Narrow therapeutic index.
- High lipophilicity.
- Long half-life.
- Metabolism-dependent activation (e.g., prodrugs).
- Route of administration (e.g., IV vs oral).

3. Disease-related Factors:

- Hepatic or renal impairment affecting metabolism and excretion.
- Cardiac disease affecting drug distribution.

Causality Assessment:

- Causality assessment refers to the process of determining whether a particular drug is responsible for an adverse reaction.

WHO-UMC Causality Assessment Scale:

- Categories:
 - Certain
 - Probable
 - Possible
 - Unlikely
 - Conditional/unclassified
 - Unassessable/unclassifiable
- Criteria include:
 - Temporal relationship
 - Dechallenge/rechallenge data
 - Alternative explanations
 - Objective evidence

Naranjo Algorithm:

- A questionnaire-based scale assigning numerical values based on:
 - Temporal association
 - Alternative causes
 - Drug levels
 - Dose-response relationship



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