# 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)

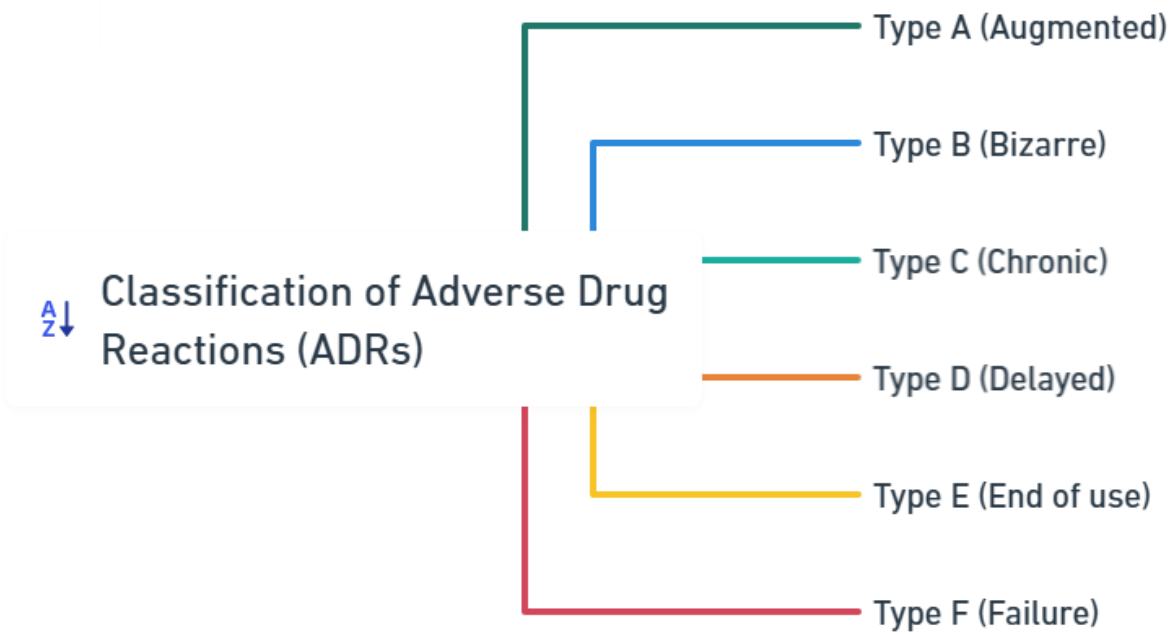
## Definition of ADR:

- 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

First Hope

FREE PREVIEW

Click here to visit our website

PHARMACY PREMIUM NOTES

# Complete subject and semesters are available on FirstHope app only.

Scan or click here

Click here to get the app >

Available on Google Play

JOIN THE FIRSTHOPE COMMUNITY

## Join our Telegram channel

Click here to join Telegram >

Scan or click here

@FirstHopeNotes

### Instagram

@firsthope.official

Click here to follow >

### YouTube channel

FirstHope-Pharmacy / Live streams

Click here to watch >

### WhatsApp channel

Follow FirstHope on WhatsApp

Click here to join >

### FirstHope website

firsthope.co.in

Click here to visit >

**B.Pharm / D.Pharm / M.Pharm / Pharm.D**

Preview notes. Complete subjects and semesters in the FirstHope app.