

UNIT-III

PHARMACOVIGILANCE METHODS



CENTURION
UNIVERSITY
*Shaping Lives...
Empowering Communities!*

RASMITA JENA
ASSISTANT PROFESSOR
SoPLS, CUTM, BBSR

- **Passive surveillance – Spontaneous reports and case series**
 - **Stimulated reporting**
- **Active surveillance – Sentinel sites, drug event monitoring and registries**
- **Comparative observational studies – Cross sectional study, case control study and cohort study**
 - **Targeted clinical investigations**

Pharmacovigilance Methods

Objective

- ✓ To establish a functional reporting system to monitor the safety of all medicines
- ✓ To learn more about the safety profile of new medicines in the early post-marketing phase
- ✓ To learn more about the ADR profile of a specific medicine(s) in your population
- ✓ To estimate the incidence of a known ADR to a specific medicine in your population
- ✓ To gather more information on the safety profile of a new chemical entity in early post-marketing phase

Methods

- Passive surveillance
 - Spontaneous reports
 - Case series
- Stimulated reporting
- Active surveillance
 - Sentinel sites
 - Drug event monitoring
 - Registries
- Targeted clinical investigations
- Comparative observational studies
 - Cross sectional study
 - Case control study
 - Cohort study
- Descriptive studies
 - Natural history of disease, Drug utilization study

Spontaneous Reports

- A communication by consumers or healthcare professionals to a company or Regulatory Authority, that describes one or more ADR in a patient, who has given the drug.
- It plays a major role in the, identification of safety signals once the drug is marketed.
- Gives alerts on rare AEs that were not detected in earlier clinical trials or pre marketing studies.
- Provides important information on at risk groups, risk factors and clinical features of known serious ADRs.

Case series

- Series of case reports can provide evidence of an association of a drug and AEs.
- Generally more useful for generating hypothesis than for verifying an association between drug exposure and outcome.
- Certain distinct adverse events occur more frequently with drug therapy, such as anaphylaxis, aplastic anemia and Stevens-Johnson syndrome events such as these are spontaneously reported for detailed and rapid follow-up.

Stimulated Reporting

- A method used to encourage and facilitate reporting by health professionals for new products, or for limited period.
- Online reporting of AE, systematic stimulation of reporting of AEs.
- Drawbacks- data are often incomplete.
Not useful to generate accurate incidence rates.

Active surveillance

- To ascertain completely the no. of AEs via a continuous pre-organized process.
E.g. follow up of patient treated with a particular drug.
- More feasible to get comprehensive data on individual AE reports.

Sentinel Sites:- Active surveillance carried out at Institutions, Nursing Homes and Hospitals etc. provides information such as data from specific patient subgroups, drug abuse etc.

Drug Event Monitoring: - Patients are identified by electronic prescription data or automated health insurance claims. A follow up questionnaire can be sent to each physician or patient at specified intervals. Information on patient demographics, indication for treatment, duration of therapy, dosage, clinical events, and reasons for discontinuation can be included in the questionnaire.

Registries: - A registry is a list of patients presenting with same characteristics. E.g. Disease registry, drug registry, pregnancy registry etc. Differs from each other depending on type of patient.

Comparative Observational Studies:-

- Traditional epidemiologic methods are a key component in the evaluation of AEs.
- Observational study designs are useful in validating signals from spontaneous reports or case series.

Cross Sectional Studies:-

- Data collected from a population of patients at a single point in time regardless of exposure or disease status.
- Primarily used to gather data for surveys or for ecological analysis. Best used to examine the prevalence of a disease at one time point or to examine trends over time, when data for serial time points can be captured.

Case Control Study:- In this case of disease are identified. Controls or patients without the disease or event of interest, are selected from the source population. Exposure status of the two groups is compared using the odds ratio.

Cohort Study:- A population at risk for the disease is followed over a time for the occurrence of the disease or events. Information on exposure status is known throughout the follow up and hence incident rates can be calculated.

Comparison cohorts of interest are selected on the basis of drug use and followed over time.

Multiple AEs can also be investigated using the same data source in a cohort study.

Targeted Clinical Investigations:-

- When significant risks are identified from pre-approval clinical trials, further clinical studies might be called, to evaluate the mechanism of action for ADRs.
- PK and PD studies might be conducted.
- Specific studies to investigate potential drug-drug interactions and food-drug interactions might be called.

Descriptive Studies:-

- Primarily used to obtain the background rate of outcome events and/or to establish the prevalence of the use of drugs in specified populations.
- Natural History of Disease- Focused on the natural history of disease, including the characteristics of diseased patient and the distribution of disease in selected populations, as well as estimating the incidence and prevalence of potential outcomes of interest.

Drug Utilization Study- These studies provide data on specific populations, such as the elderly, children, or patients with hepatic or renal dysfunction, often stratified by age, gender, concomitant medication, and other characteristics.