II Semester Mpharm (Pharmacology) – 204 T Clinical research and Pharmaco vigilance
5th Unit

Pharmacoepidemiology

Pharmacoepidemiology is the study of the utilization and effects of drugs in large numbers of people; it provides an estimate of the probability of beneficial effects of a drug in a population and the probability of adverse effects.

It can be called a bridge science spanning both clinical pharmacology and epidemiology.

Definition

It defined as "the application of epidemiologic reasoning methods and knowledge to the study of the uses and effects both the beneficial and adverse effects of drugs in human population."

Populations are large groups of people, which may include thousands or even millions of people.

Role of pharmocoepidemiological research

Evaluation of specific drug use in certain conditions.
Patterns of drugs use, that is how it is being used how-much, where, when and by whom.
Drug taking behaviours in society.
WHO targets its pharmacoepidemiological efforts to ensure the quality, safety, and efficacy of drugs.

The pharmacoepidemiology studies focus on;

Global trends in prescribing
Appropriateness of drug use
Medication adherence
Lifestyle effects on drug therapy
Specific age population drug therapy
Drug interactions
Predictable ADRs
Uncommon and unpredictable ADRs
This study can be divided into two main types:
Observational study
Intervention study

Observational studies

In this study the investigator measures but does not intervene..
In this study there are divided into two types of study according to the study procedure.
Descriptive study
Focus on the description of the occurrence of a disease in a population.
To generate hypothesis
To permit evaluation of trends in health and comparison among countries and subgroups within countries.

To provide basis for planning, provision anmd evaluation of health services.
To identify problems to be studied by analytical methods and to suggest areas that may be useful for investigation.
The study involves,
Ecological
Case report
Case series
Cross sectional
Analytical study
Cross sectional
Case control
Cohort study
Hybrid design.

Intervention studies

This study involve an active attempt to change a disease determinant or the progress of a disease.

The studies are based on a group which has had the experience compared with control group which has not had the experience.

It involves,
Clinical trials
Field trials
Community intervention study

Pharmacoeconomics

A study evaluates the cost and effects of a pharmaceutical product.

Pharmacoeconomic research identifies, measures & compares the costs (resources consumed) and consequences of pharmaceutical products & services.

Pharmacoeconomic analysis,
Efficient allocation of limited resources among competing alternative medications and services.
Biggest bang for your bucks, using a quantitative measures.
To make the best use of limited resources
Importance of pharmacoeconomics
Helps to decide which drug to develop
To estimate and understand the full impact of new therapy
To make an informed decision regarding appropriate use of drug which have been developed.

Goals:

To determine which healthcare alternatives provide the best health care outcomes in terms of money spent.

To improve the allocation of resources for pharmaceutical products and services.

Costs,

Costs involves all the resources that are used to produce and deliver a particular drug therapy
Types of costs.

Direct costs
Indirect costs
Intangible costs
Opportunity costs
Direct medical costs;
Costs of medical services,
These include:
Fixed costs or costs that do not vary immediately with the number of patients treated. E.g. cost of hospital building or equipment etc.,
Variable costs or costs that vary immediately with number of patients treated. E.g. cost of drugs, syringes, needles etc.,

Direct non-medical cost;
Costs incurred by the patient in receiving medical care. E.g. transportation to and from hospital.

Indirect cost:
Lost workdays
Lost productivity at work
E.g. income lost because absenteeism, loss of productivity.
Intangible cost:
Costs of pain, worry and other suffering which a patient or his family might suffer.
Opportunity costs:
The amount lost by not using economic resources in its best alternatives use.(labour, capital, building, management etc.,)
Resources invested in one area will be at expense of loss of another opportunity.
Safety pharmacology
Safety pharmacology is a branch of pharmacology specialising in detecting and investigating potential undesirable pharmacodynamic effects of new chemical entities(NCEs) on physiological function in the therapeutic range and above.
Pharmacodynamics
Primary pharmacodynamic effects
• Studies on the mode of action and/or effects of a substance in relation to its desired therapeutic target.
Secondary pharmacodynamic effects
• Studies of the mode of action and /or effects of a substance not related to its desired therapeutic target.

Dose level of safety pharmacology
Doses should include and exceed the primary pharmacodynamic or therapeutic range. In the absence of adverse effects on safety pharmacology parameters, the highest tested dose should produce moderate adverse effects in this or in other studies of similar route and duration. These adverse effects can include dose-limiting pharmacodynamic effects or other toxicity.

In practice, some effects in the toxic range (e.g. tremors or fasciculations during ECG recording) may confound the interpretation of the results and may also limit dose levels.

Adverse effects in vital function systems

Central Nervous System - Convulsion, disturbance of consciousness, etc.
Cardiovascular Functions - Arrhythmia, circulatory shock, etc.
Respiratory Functions - Bronchospasm, respiratory failure, etc.

SP studies may not be necessary for:

• locally applied agents (e.g. dermal or ocular), where pharmacology well characterized and where systemic exposure low.

• cytotoxic agents for treatment of end-stage cancer patients, but cytotoxic agents with novel mechanism of action: yes.

biotechnology-derived products

• achieve highly specific receptor targeting
• SP endpoints in toxicology and/or
• PD studies additional exception: e.g. new salt having similar pharmacokinetics and pharmacodynmamics.

Safety pharmacology timing

(Prior to First Administration in Humans Core battery, follow-up or supplemental studies based on a cause for concern.

(During Clinical Development To clarify observed or suspected undesirable effects in animals and humans.

(Before Approval - Supplemental studies unless not warranted safety pharmacology endpoints covered in other studies.

Concerns may arise from:

• safety pharmacology core battery
• clinical trials
• pharmacovigilance
• experimental in vitro or in vivo studies
• literature reports