DEPTH OF BIOLOGY

Unit - 6

Pharmacoepidemiology, pharmacoeconomics, safety pharmacology

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Pharmacoepidemiology

Pharmacoepidemiology is a branch of science that combines pharmacology (the study of drugs) and epidemiology (the study of diseases in populations).

It deals with the use and effects of medicines in large groups of people.

In simple words: it studies "what medicines do to people in the real world."

While clinical trials provide information on safety and effectiveness of drugs before marketing, they involve limited patients, short duration, and controlled settings.

Pharmacoepidemiology extends this by studying drugs in general populations over longer periods, providing more realistic data.

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Pharmacoepidemiology

Pharmacoepidemiology is defined as:

"The study of the utilization and effects of drugs in large numbers of people."

It is often called the bridge between clinical pharmacology and public health.

Aims and Objectives-

To study patterns of drug use in populations.
To evaluate effectiveness of medicines in real-world practice.
To detect and assess adverse drug reactions (ADRs).
To assess benefit–risk ratio of drugs.
To study the economic impact of drug use.
To provide data for drug policy, guidelines, and rational use of medicines.

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Scope of Pharmacoepidemiology-

Drug utilization studies → How drugs are prescribed, distributed, and used.

Pharmacovigilance → Monitoring safety and ADRs after marketing.

Comparative effectiveness research → Which drug works better in real-world conditions.

Evaluation of drug safety in special groups (pregnant women, children, elderly).

Public health programs → e.g., vaccine safety and effectiveness monitoring.

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Methods in Pharmacoepidemiology-

Pharmacoepidemiology mainly uses epidemiological study designs:

1. Descriptive Studies-

Describe who uses drugs, how, and for what conditions.

Examples: Drug prescription patterns, antibiotic use in hospitals.

2. Analytical Studies-
These try to find cause–effect relationships between drug use and outcomes.

-Cohort Studies
Compare people who use a drug vs. those who don't.
Measure Relative Risk (RR).
Example: Studying if oral contraceptives increase risk of blood clots.

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Case-Control Studies

Compare patients with ADR (cases) vs. those without (controls).

Measure Odds Ratio (OR).

Example: Association of aspirin use with Reye's syndrome.

Cross-sectional Studies

Snapshot at one point in time.

Example: Prevalence of self-medication in a community.

Randomized Controlled Trials (RCTs) (sometimes included)

Best method for causality but limited by small sample and high cost.

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Sources of Data-

Pharmacoepidemiology uses many sources of information:

Spontaneous reporting systems (e.g., VigiBase, VAERS, EudraVigilance).

Prescription databases (hospital/pharmacy records).

Electronic health records (patient medical histories).

Registries (cancer registry, pregnancy registry).

Surveys and field studies in communities.

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Applications-

Detecting rare and serious ADRs not found in trials.
Monitoring long-term safety of medicines.
Evaluating effectiveness of vaccines in populations.
Studying patterns of drug abuse and misuse.
Supporting regulatory decisions (warnings, restrictions, withdrawal).
Helping in formulary management and rational drug policies.

Advantages-

Provides real-world data beyond clinical trials.
Can study large populations over long periods.
Detects rare ADRs.
Helps in public health planning and policy.

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Limitations-

May suffer from confounding factors (e.g., other diseases, multiple drugs).

Bias in reporting (underreporting or selective reporting).

Data may be incomplete or inaccurate.

Cannot always prove causality (only association).

Relation with Pharmacovigilance-

Pharmacovigilance = monitoring and reporting of ADRs.

Pharmacoepidemiology = provides scientific methods to analyze those reports and confirm risks.

Both work together to ensure safe and effective use of medicines.

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Pharmacoeconomics

Medicines and healthcare are becoming more advanced, but also more expensive. Governments, hospitals, and insurance companies cannot provide all treatments to everyone due to limited resources.

Therefore, we need to decide which medicines give the best results for the money spent.

The branch of science that helps in this decision-making is called Pharmacoeconomics.

It combines pharmacy (drug use) with economics (cost and benefit analysis).

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Pharmacoeconomics is defined as-

"The scientific discipline that compares the costs and consequences of pharmaceutical products and services."

In simple words → Pharmacoeconomics studies how much a drug costs and what benefits it provides, to see if it is worth using.

Objectives of Pharmacoeconomics-

To provide data for healthcare decision-making.

To compare the value of one medicine vs. another.

To support formulary selection (which drugs should be in hospitals/insurance lists).

To promote rational drug use.

To help governments and hospitals in budget allocation..

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Need for Pharmacoeconomics-

High cost of new medicines (e.g., anticancer, biologicals, vaccines).

Limited healthcare budgets, especially in developing countries.

Pressure on hospitals and insurance providers to control costs.

Requirement by regulatory authorities in many countries before approving a new drug.

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Types of Pharmacoeconomic Evaluations-

Pharmacoeconomic studies compare costs (inputs) and outcomes (results) of drugs.

1. Cost-Minimization Analysis (CMA)-

Used when two drugs have the same effectiveness.
The cheaper one is preferred.

Example: Two brands of paracetamol – both give same relief, so choose the cheaper.

2. Cost-Effectiveness Analysis (CEA)-

Compares cost with clinical outcomes (like reduced BP, reduced cholesterol).

Outcomes are measured in natural units (mmHg, % cure rate, number of lives saved).

Example: Compare two anti-hypertensive drugs based on cost per mmHg reduction in BP.

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3. Cost-Utility Analysis (CUA)-

Outcomes are measured in quality of life units, such as:
QALY (Quality Adjusted Life Years)
DALY (Disability Adjusted Life Years)
Example: Cancer drug extends life by 2 years but with side effects. Another drug extends by 1.5 years with better quality of life. CUA helps decide which is better value.

4. Cost-Benefit Analysis (CBA)-

Both costs and benefits are measured in money terms.

Example: If vaccination costs $1 million but saves $5 million in hospital expenses, it is cost-beneficial.

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Types of Costs in Pharmacoeconomics-

1. Direct Costs-
Medical: hospital stay, drugs, tests.
Non-medical: travel expenses, caregiver costs.

2. Indirect Costs-

Productivity loss due to illness.
Time lost from work.

3. Intangible Costs-
Pain, suffering, anxiety (hard to measure).

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Applications of Pharmacoeconomics-

Drug formulary management in hospitals.
Policy decisions for government-funded programs.
Health insurance reimbursement.
Pricing of new medicines.
Cost justification of expensive therapies like gene therapy or immunotherapy.
Encouraging rational prescribing by comparing cheaper but equally effective alternatives.

Advantages-

Helps in efficient use of resources.
Provides scientific data for drug pricing and policy.
Encourages cost-effective and rational therapy.
Improves patient outcomes by selecting drugs with best benefit-to-cost ratio.

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Safety Pharmacology

Before a new drug is approved for human use, it must be tested for safety.

Even if a medicine is effective, it should not cause serious harm to vital organs like the heart, lungs, or brain.

Safety pharmacology is the science that studies the undesired effects of new drugs on vital physiological functions.

It is an important part of non-clinical drug development and is required by regulatory authorities worldwide.

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According to ICH (International Council for Harmonisation):

Safety pharmacology is the study of the potential undesirable pharmacodynamic effects of a substance on physiological functions in relation to exposure in the therapeutic range and above.

In simple words:
Safety pharmacology = testing drugs to see if they harm essential body systems.

Objectives of Safety Pharmacology-

To identify and evaluate unwanted effects of drugs on vital organs.
To ensure that new drugs are safe before clinical trials in humans.
To support dose selection for human studies.
To protect patients by reducing the risk of dangerous side effects.
To meet regulatory requirements for drug approval.

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Core Battery of Safety Pharmacology Studies

Regulatory guidelines (ICH S7A and S7B) specify that all new drugs must be tested on three vital systems:

Central Nervous System (CNS)-
Tests for: movement, behavior, coordination, sleep, body temperature.
Example: checking if drug causes seizures or sedation.

Cardiovascular System-
Tests for: blood pressure, heart rate, ECG changes.
Example: drugs that prolong QT interval may cause arrhythmias.

Respiratory System-
Tests for: breathing rate, oxygen level, airway resistance.
Example: checking if drug causes respiratory depression.

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Follow-up and Supplemental Studies

If problems are found in the core systems, extra studies are done:

Renal system → urine output, kidney function.

Gastrointestinal system → motility, secretion.

Immune system → hypersensitivity, allergic reactions.

Reproductive system → fertility, pregnancy safety.

Types of Safety Pharmacology Studies

1. In vitro studies-

Performed outside the body (e.g., cell cultures, isolated tissues).

Example: testing drug effect on ion channels in heart cells.

2. In vivo studies-

Performed in living animals.

Example: testing drug effects on blood pressure in rats or dogs.

3. Ex vivo studies-

Performed on isolated organs taken from animals after drug administration.

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#Applications of Safety Pharmacology-

Ensures safe drug development.
Detects toxic effects early, preventing harm to humans.
Helps in deciding whether to continue or stop drug development.
Provides data for drug labeling and warnings.
Protects pharmaceutical companies from financial loss due to unsafe drugs.

#Advantages-

Protects patient safety.
Identifies life-threatening side effects early.
Provides scientific evidence for regulatory approval.
Improves benefit–risk ratio of drugs.

Limitations

-Animal results may not always predict human effects.

-Expensive and time-consuming.
Cannot detect all rare adverse events.

-Some long-term safety issues may appear only after market use.

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