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SCOPE OF PHARMACOLOGY

- According to history many scientist contributed to the concepts of pharmacology. Rudolf Buchheim (1820-1879) was the originator pharmacology as an experimental science in 1847 in Germany Later on in 19th century
  - ★ Father of Pharmacology- Oswald Schmiedeberg
  - ★ Father of American Pharmacology- John Jacob Abel
  - ★ Father of Indian Pharmacology- Colonel ram Nath Chopra
  - ★ Father of clinical pharmacology- Loise Lasagna
- In 1805, Friedrich Serturner discovered morphine which has pharmacological activity as analgesic.
- Progressively with the passage of time various more drugs are introduced by the scientist which show specific pharmacological effects

→ Greiger and Hassie(1833) – atropine
→ Vogt (1907) – histamine
→ P.Gleno (1908) – Sulfanilamide
→ Abel (1919) – Oxytocin
→ Banting and Best(1922) - Insulin
→ A.Flemming(1928) – Pencillins → Domagk (1932) – Sulfonamide
→ Edward C. Kendall – Cortisone
→ Waksman (1944) – streptomycin
→ Bartz (1948) – Chloremphenicol
Duggar (1948) – tetracyclin
→
→ Cade (1950)- Lithium

❖ SCOPE-

- An area in which something
  - Act or
  - Operates or
  - has power or control
- Main areas are- A. Research
  - B. Academics
  - C. Clinical pharmacology
  - D. Industries
  - E. Pharmacovigilance
  - F. Pharmacoeconomics
  - G. chronopharmacology

A. Research -It can be divided into two category

a) Forward approach or classical approach and
b) Reverse pharmacology or target based screening

a) Forward approach or classical approach- there are three stages of drug development

1) Drug discovery
   i) Random screening
   ii) Serendipity(संयोगवश कु छ अच्छा मिल ाना)
   iii) Rational drug designing
   iv) Designing of prodrug or active metabolite as drug

2) Preclinical phase/experimental phase

- To satisfy all requirements that are needed before a compound is considered fit to be tested in humans Require 1-2 year
- Out of 10,000 compounds screened only 10 qualify for preclinical evaluation
- Deals with effect of various pharmacological agents on different animal species

➢ **Aim**

- Find out therapeutic agent suitable for human use
- Study of toxicity of the drugs
- Study the mechanism and site of action of drugs

➢ **Done by**

 In vitro study- receptor characterisation, enzyme inhibition, cytokine activity
In vivo study- Animal experiments

3) Clinical trial phase- in this systematic study of new drug in human subjects

- **Phase-1**- in this phase subjects Healthy Volunteers (25-100) to determine the safe dose, pharmacokinetic and any predictable toxicity
- **Phase-2**- in this phase subjects are patient with target disease to determine the efficacy and definitive end point(how patients feel, function and survive)
- **Early phase-2** In this subject increase to 200 patient with single blind(A type of clinical trial in which only the researcher doing the study knows which treatment the participant is receiving until the trial is over.)
- **Late phase 2-** in this subject increase to 200-200 patient with double blind(A type of clinical trial in which neither the participants nor the researcher knows which treatment participants are receiving until the clinical trial is over.)
- **Phase-3**- in this phase subjects increase to 1000-5000+ to further establish safety and efficacy These 3 phase take 5-6 years
- Filling of New drug application
- Phase-4 – this is a post licensing phase and has no fixed duration. In this phase periodic safety report(PSUR) is to be submitted

b) Reverse pharmacology or target-based screening-

- Reverse pharmacology (target-based screening) began with the growth of molecular biology
- It starts with the identification of a molecular target (protein; enzyme, receptor, etc.) that is involved in the pathophysiology of a disorder or disease
- Then potential ligands (compounds) are screened through binding assay where the highly selective ligand that binds with the molecular target is identified. This is a process known as 'ligand fishing'.
- Then this potential ligand (compound) undergoes functional studies (animal models) to show the desired physiological effect.
- Once experimental results are consistently significant, clinical studies can began.
- Reverse pharmacology speed up the process, provide clear understanding of the mechanism of action, optimize safety as well as increase efficiency (highly selective and potent) of the drug.

B. ACADEMICS

i) **Undergraduate education**

- Introduction to drugs
- Mechanisms of action
- Prescription writing
- Pharmaceutical preparation
- Identification of adverse drug reaction

ii) **Post graduate education**

- Basic research
- Experimental pharmacology
- Pharmacokinetics and pharmacodynamics
- Pharmacovigilance
- Clinical pharmacology
- Therapeutic drug monitoring

C. CLINICAL PHARMACOLOGY

- Term coined by Harry Gold in 1950s
- It uses basic science of pharmacology and apply pharmacological principles and method in the real world It connect basic science and clinical science
- It is a platform for collaborative efforts between academia and pharmaceutical industry.
- **Frontiers of clinical pharmacology are**

i) Clinical trails ii) BA/BE studies

- BA(Bioavailability)- BA studies help in deciding the dose of drugs
- BE(Bioequivalent)- when two drugs expected to be same for all intents and purposes

iii) Prescription audit- To develop a list of essential drugs

iv) Antibiotic stewardship- to improve the use of antimicrobial medications to

→ Enhance patient health outcomes
→ Reducing resistance to antibiotics
→ Decreasing unnecessary cost

v) Drug use survey

 Study of the marketing, distribution, prescription and use of drugs in a society with special emphasis on the result of medical, social and economic consequences

vi) Rational use of medicine

- Appropriate medication
- To check safety, tolerability efficacy and price (STEP criteria)
- Correct dispensing and appropriate instruction to patient
- Adequate monitoring of patient adherence to the treatment
- Watch for adverse effect of drug

vii) Therapeutic drug monitoring (TDM) service- it is testing that measures the amount of certain medicines in your blood. It is done to make sure the amount of medicine you are taking is both safe and effective.

D. INDUSTRIES

i) Research: New drug development ii) Medical advisor

- Analysis of health of population
- Evaluation of primary care service
- Planning of services
- Advice on effective prescribing
- Education for general practitioner

iii) Medical transcription

 The process of transcription or converting voice-recorded reports as directed by physician or other healthcare professional into text format

iv) Medico marketing

 Business of adverting or promoting sale of pharmaceutical or drugs

v) Product management vi) Contract research organisation

- A service organisation that provides support to the pharmaceutical and biotechnology industries in the form of outsourced pharmaceutical research services, for both drugs and medical devices.

vii) Training

- To medical representatives
- To physician
- Academy for clinical excellence (ACE)- The Academy for Clinical Excellence (ACE) is the pioneering clinical research training institute in India established in February 2002
- Indian society for clinical research (ISCR)

E. PHARMACOVIGILANCE (Pharmakon- Drug, Vigilare- To keep Watch)

- Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem.
- The role of pharmacovigilance can be divided into three main areas

i) To identify, quantify and document drug related problem ii) To contribute to reduce the risk of drug related problem in health care system iii) To increase knowledge and understanding of factors and mechanisms which are responsible for drug-related injuries.

F. PHARMACOECONOMICS

- It is a branch of health economics which particularly focuses upon the costs and benefits of drug therapy
- It is an innovative method that aims to decrease health expenditures while optimising health care results
- It involves two major methodologies- i) Cost analysis and ii) Cost outcome
- Pharmacoeconomics is used to determine which drug should be included in the formulary by choosing the most effective treatment at the lowest price.

G. PHARMACOEPIDEMIOLOGY

- It is the study of drugs among people Pharmakon =

Drugs
Epi = among
Demos = people
Logous = study

- It is study of use and effect of drugs in large number of people
- It involves-

i) Casuality and incidence of adverse drug reactions ii) Effectiveness of new drugs in defined population iii) Pattern of prescribing in a particular health care facility area iv) Strategy to improve prescribing v) Economic impact of drug use

H. CHRONOPHARMACOLOGY

- Chronopharmacology is the science dealing with the optimization of drug effects, and the minimization of adverse effects by timing medication in relation to the biological rhythm

EX- Evening dosing has become standard for H_2 receptor antagonists, because **available agents inhibit nocturnal basal acid secretion more effectively than daytime stimulated secretion**

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