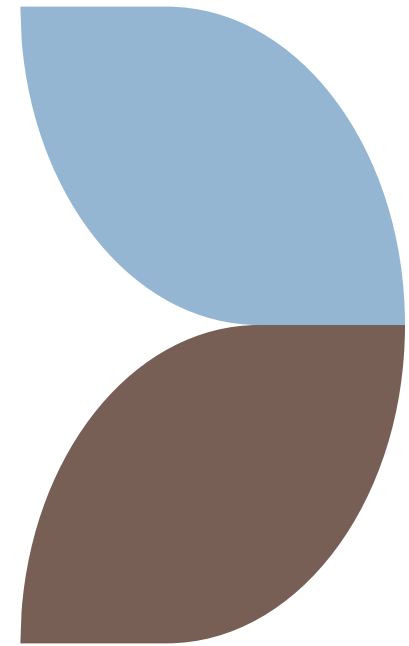


# **Introduction to Scientific Research**

**Dr. Mohammed Essam**

**Head of Physical Therapy  
Department for Surgery  
South Valley University**



# Key Lecture Concepts

- 1. Understanding the process described as “the scientific method”.**
- 2. The role of a hypothesis in a research study.**
- 3. Strategies underlying hypothesis formulation.**
- 4. The manner to frame your hypothesis statement.**



# Research is .....

## Knowledge acquisition gained.....

- Through **reasoning**.
- Through **intuition**.
- But most importantly through the use of **appropriate methods**.



# Basic Elements of The Scientific Method of Research

- 1) Empiricism: the notion that enquiry is conducted through **observation** and **knowledge** that verified through **evidence**.
- 2) Determinism: the notion that events occur according to **regular laws and causes**. The goal of research is to **discover** these laws and causes.
- 3) Skepticism: the notion that **any proposition** is open to **analysis** and **critique**.



# Steps of Scientific Method

- 1. Choose a question to investigate.**
- 2. Identify a hypothesis related to the question.**
- 3. Make testable predictions in the hypothesis.**
- 4. Design an experiment to answer hypothesis question.**
- 5. Collect data in experiment.**
- 6. Determine results and assess their validity.**
- 7. Determine if results support or refute your hypothesis.**



# The Scientific Method

**1. Suspicion that** a factor (exposure) may influence occurrence of disease or a noted health outcome:

- a.** Observations in clinical practice.
- b.** Examination of disease/outcome patterns.
  - Do subpopulations have higher or lower rates?
  - Are disease rates increased by certain factors?
- c.** Observations in laboratory research.
- d.** Theoretical speculation.



# The Scientific Method

## 2. Identify variables you are interested in:

- **Exposure (independent):-** risk factor, protective factor, predictor variable, treatment.
- **Outcome (dependent):-** disease, event.



**Three essential characteristics that we look to measure in studies are...**

---

**Person**

**Place**

**Time**





# Person

*“Since disease not does occur at random”*

- **What kinds of people tend to develop a particular disease?**
- **Who tends to be spared?**
- **What’s unusual about those people?**



# Person Factors

---

- **Age, gender, race, ethnicity.**
- **Education, occupation.**
- **Genetic predisposition.**
- **Concurrent disease.**
- **Diet, exercise, smoking.**
- **Risk taking behavior.**



# Place

*“Since disease not does occur at random”*

- **Where is the disease especially common or rare?**
- **What is different about those places?**

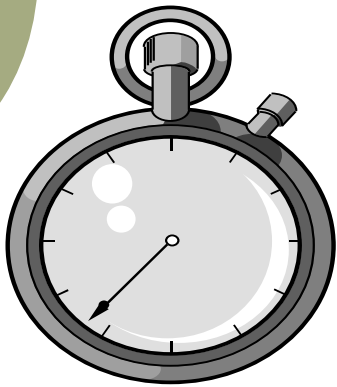


# Place Factors

---

- **Geographic place.**
- **Residence.**
- **Occupation.**
- **Climate.**
- **Geology.**
- **Population density.**
- **Economic development.**
- **Nutritional practices.**
- **Medical practices.**





# Time

*“Since disease not does occur at random”*

- How does disease frequency change over time?
- What other factors are temporally associated with those changes?

# Time Factors

---

- **Calendar Time / Time of Day.**
- **Time since an event.**
- **Date of onset.**
- **Age (time since birth in the young).**
- **Seasonality.**
- **Temporal trends.**



# The Scientific Method

## 3. Formulate a specific hypothesis:

- ❑ Frame a hypothesis which seeks to **answer a specific question** about the **relationship** between an exposure and an outcome.



# Basic Question in Research

**Are exposure and disease/outcome linked?**

**Is there an association between them?**

**E**



**D**

Exposure

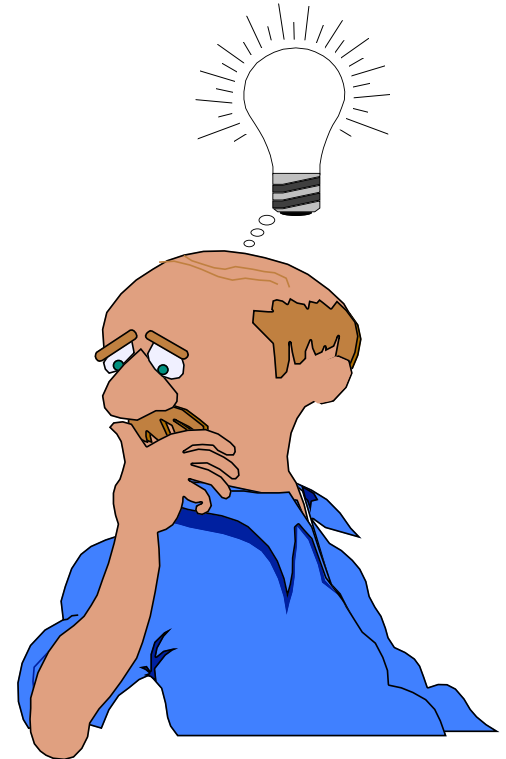
Disease / Health Outcome





# Hypothesis Formulation

- A. Formulate a hypothesis.**
- B. Frame the hypothesis in a format that is testable.**
- C. Test the hypothesis.**



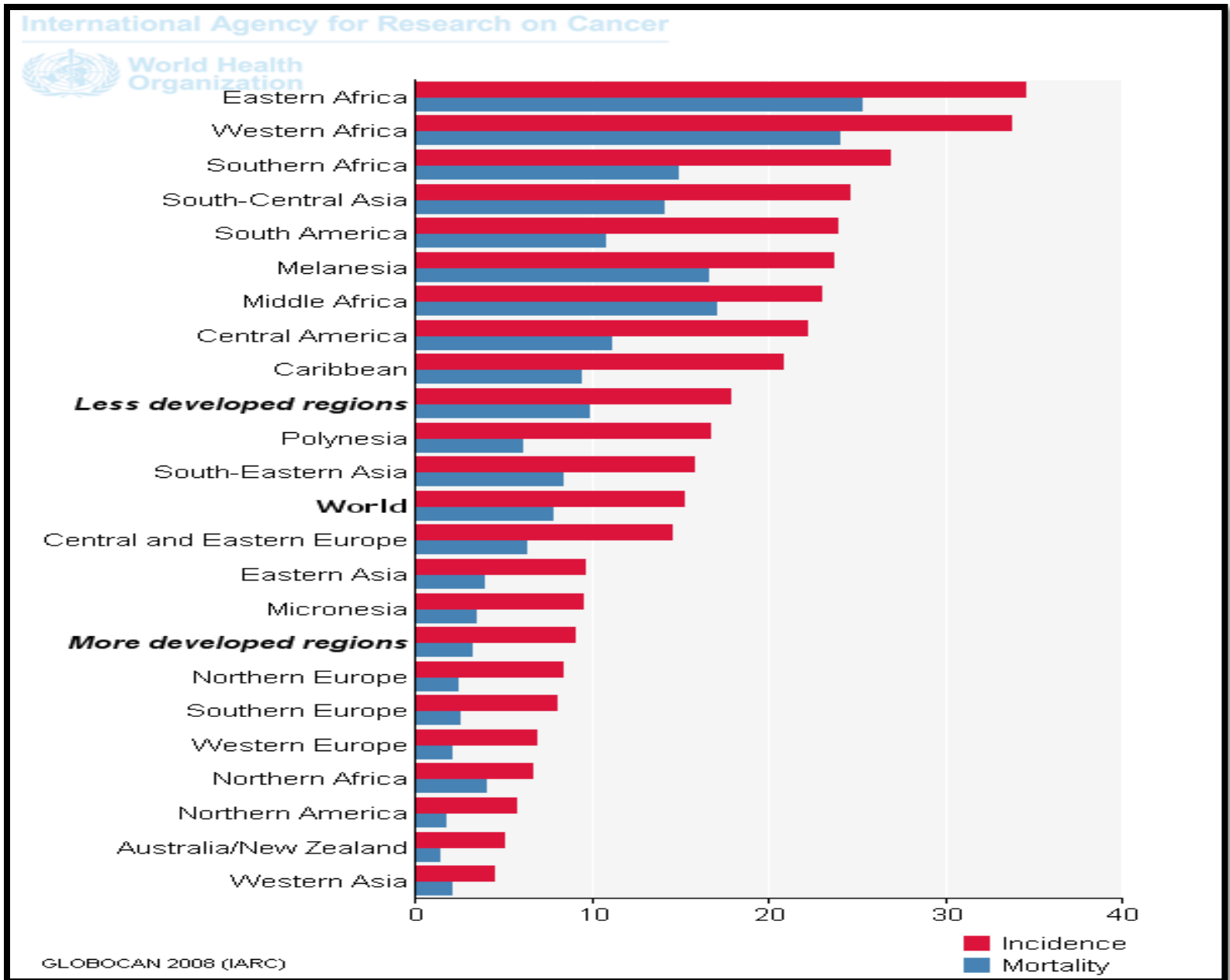
# Hypothesis Formulation

## Observations from:

- ❖ **Literature (review PubMed on topic area).**
- ❖ **Natural experiments (e.g. migrant studies).**
- ❖ **Multi-national comparisons.**
- ❖ **Descriptive studies (assessment of person, place, and time characteristics).**
- ❖ **Creativity.**



# Cervical Cancer



- **Infectious and chronic diseases show great variation from one country to another.**
  - **Some differences may be attributed to:**
    - **Cultural factors.**
    - **Genetics.**
    - **Climate.**
    - **Diet.**

# 4. Design Study

- **Formally test the identified hypotheses in a **research study**.**
- **The study should follow a **specific plan** or **protocol** (the study design).**
- **Study designs direct how the investigation is **conducted** and allows for the translation of a **conceptual hypothesis** into an **operational one**.**



# 4. Design Study

## Study Designs .....

- A. Randomized controlled clinical trial.**
- B. Cross-sectional.**
- C. Case-control.**
- D. Case series.**
- E. Cohort.**



## 5. Association:

From the **results** of your study, does a **statistical relationship** exist between **two or more events, characteristics, or other variables**



Is there a **statistical relationship, or association,** between exposure and disease/outcome?



# Statistical Association

The degree to which rate of disease or outcome in persons with a specific exposure is either higher or lower than rate of disease or outcome among those without that exposure.



# Basic Question in Research

**Are exposure and disease/outcome linked?**

**Is there an association between them?**

**E**



**D**

Exposure

Disease / Health Outcome



## **6. Assess validity of association:**

- **Does the observed association really exist?**
- **Is the association valid?**
- **Are there alternative explanations for the association?**
  - **Chance.**
  - **Bias.**
  - **Confounding.**



# Remember

**Discoveries or hypotheses are sometimes resisted because they seem counter-intuitive.**





Thank

You

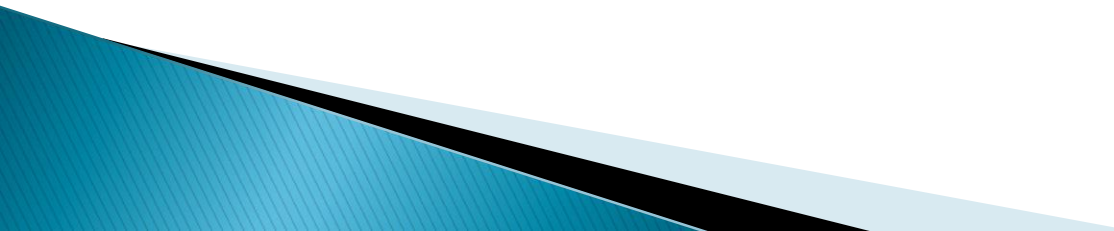


# Study Designs


# Purpose of studies

- 1) Assess the health status or clinical characteristics of a well-defined population or group of subjects.
  - The immunization status of children in the community.
  - The incidence of measles in a locality.

## 2) Probe the natural history of disease.

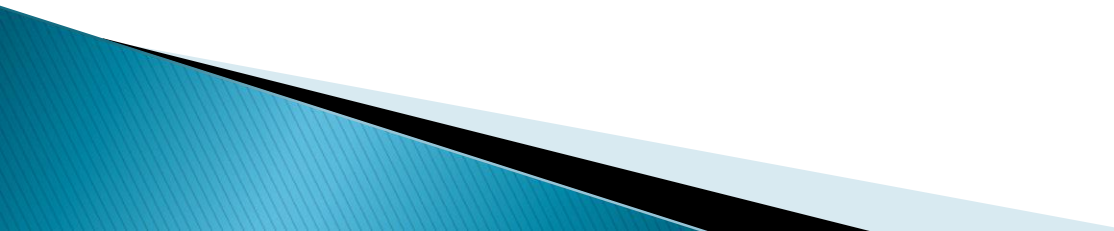
- The clinical course of retinopathy in diabetics over a 10-year follow-up period.
  - The prognosis of patients with a solitary calcified pulmonary nodule.
- 

### 3) Examine clinical decision-making processes.

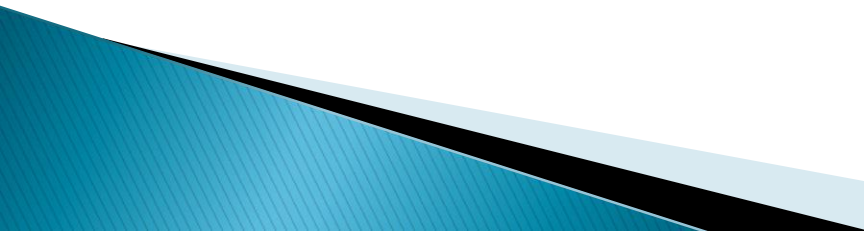
- **The best screening test for glaucoma in the general population by general practitioners.**
  - **The likelihood of colorectal cancer in patients with bright red blood per rectum.**
- 



#### **4) Determine and assess treatment outcomes.**

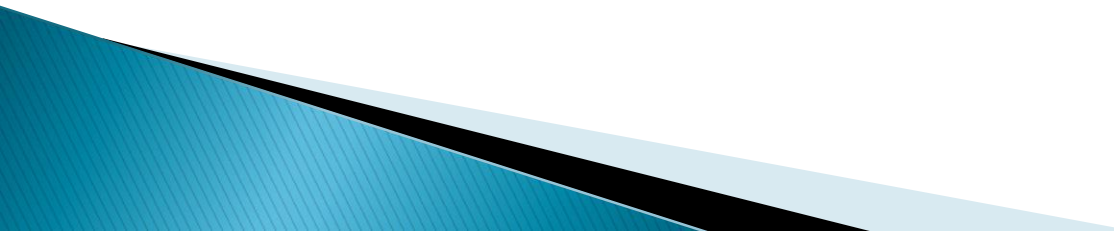
- Tumor response of laryngeal cancer in patients who receive radiation treatment.**
  - Benefit of medical treatment versus coronary artery bypass surgery for angina pectoris.**
- 

## 5) Identify and assess risk factors.

- **The incidence of lung cancer among smokers.**
  - **The likelihood of colorectal cancer in patients with colonic polyps.**
- 

# The suitable study designs

The type of study chosen depends on:

- the type of problem;
  - the knowledge already available about the problem; and
  - the resources available for the study.
- 

STATE OF KNOWLEDGE OF THE PROBLEM	TYPE OF RESEARCH QUESTIONS	TYPE OF STUDY
Knowing that a problem exists but knowing little about its characteristics or possible causes.	<ul style="list-style-type: none"> <li>• What is the nature/magnitude of the problem?</li> <li>• Who is affected? How do the affected people behave? What do they know, believe, think about the problem and its causes?</li> </ul>	<p><i>Exploratory studies, or Descriptive studies:</i></p> <ul style="list-style-type: none"> <li>• Descriptive case studies</li> <li>• Cross-sectional surveys</li> </ul>
Suspecting that certain factors contribute to the problem.	<ul style="list-style-type: none"> <li>• Are certain factors indeed associated with the problem? (e.g., Is lack of pre-school education related to low school performance? Is low fibre diet related to carcinoma of the large intestine?)</li> </ul>	<p><i>Analytical (comparative) studies:</i></p> <ul style="list-style-type: none"> <li>• Cross-sectional comparative studies</li> <li>• Case-control studies</li> <li>• Cohort studies</li> </ul>
Having established that certain factors are associated with the problem: desiring to establish the extent to which a particular factor causes or contributes to the problem.	<ul style="list-style-type: none"> <li>• What is the cause of the problem?</li> <li>• Will the removal of a particular factor prevent or reduce the problem? (e.g., stopping smoking, providing safe water)</li> </ul>	<ul style="list-style-type: none"> <li>• Cohort studies</li> </ul> <p><i>Experimental or quasi-experimental studies</i></p>
Having sufficient knowledge about cause(s) to develop and assess an intervention that would prevent, control or solve the problem.	<ul style="list-style-type: none"> <li>• What is the effect of a particular intervention/strategy? (e.g., treating with a particular drug; being exposed to a certain type of health education)</li> <li>• Which of two alternate strategies gives better results? Which strategy is most cost-effective?</li> </ul>	Experimental or quasi-experimental studies

# Type Of Clinical Question

## 1. Background Question:

- General Knowledge about a disorder
- e.g. What causes Hypertension ?

## 2. Foreground Question:

- Specific knowledge about managing a disorder.
- e.g. In tense ascites, is taping superior to diuretics ?

# Formulate A Question

**P**

▶ Patient or population

**I**

▶ Intervention or exposure

**C**

▶ Comparison intervention

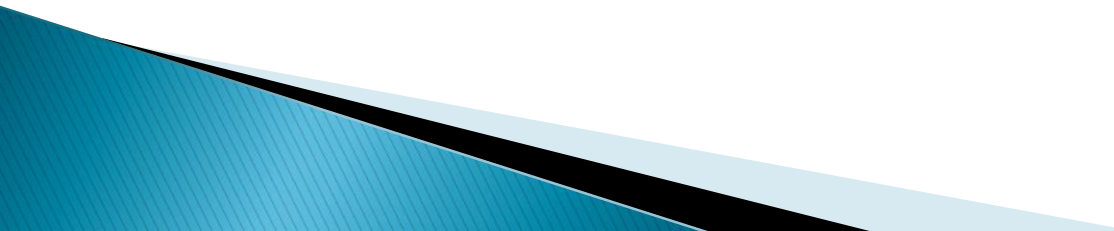
**O**

▶ Special clinical Outcome(s)

<b>P</b>	<b>I</b>	<b>C</b>	<b>O</b>
<b>Patient, Population or Problem</b>	<b>Intervention or exposure</b>	<b>Comparison</b>	<b>Outcome</b>
<p>What are the characteristics of the patient or population?</p> <p>What is the condition or disease you are interested in?</p>	<p>What do you want to do with this patient (e.g. treat, diagnose, observe)?</p>	<p>What is the alternative to the intervention (e.g. placebo, different drug, surgery)?</p>	<p>What are the relevant outcomes (e.g. morbidity, death, complications)?</p>

# Major Types of Studies

## I. Descriptive

- Case Report
  - Case Series
  - Ecologic Studies
  - Cross sectional surveys
- 



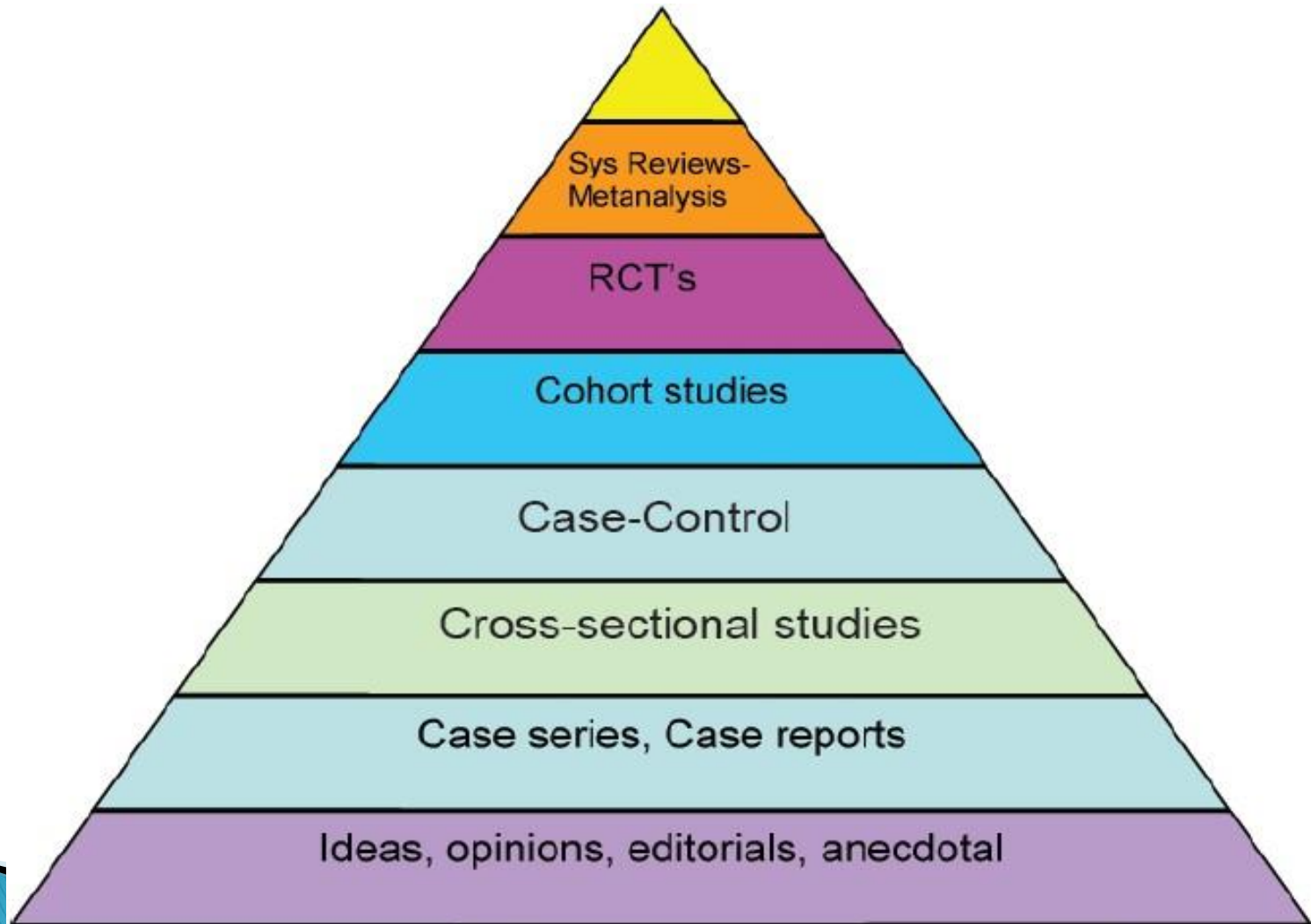
# Major types of studies:

## II. Analytic

A) Observational

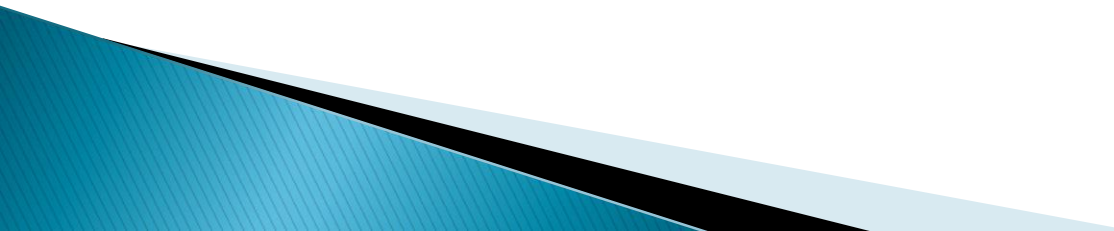
B) Experimental

# Hierarchy of Evidence



# Major Types of Studies

## I. Descriptive

- Case Report
  - Case Series
  - Ecologic Studies
  - Cross sectional surveys
- 

# Major types of studies: II. Analytic

## A) Observational

- Cross-sectional or prevalence Studies
- Retrospective (case control, Case referent)
- Prospective
  - Cohort or concurrent prospective.
  - Historical or retrospective or non-concurrent prospective.

## B) Experimental

### ▶ Clinical Trials

- Therapeutic trials
- Intervention trials
- Prevention trials

### ▶ Community Trials

- (controlled interventions)
- (comparative experimental)

# Case Report

A brief, objective report of a clinical characteristic or outcome from a single clinical subject or event

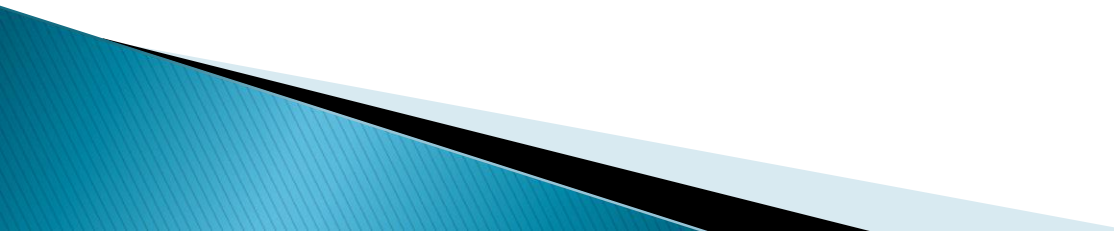
- ▶ Can address almost any clinical question or issue, including screening test results or treatment outcomes, or natural history.
- ▶ Commonly used to report unusual or unexpected events, such as
  - adverse drug reactions,
  - previously unrecognized disease, or disease characteristic

## EXAMPLE:

- ▶ **Advanced proliferative diabetic retinopathy in a patient with no other clinical evidence of diabetes**

# Case Series

An objective report of a clinical characteristic or outcome from a group of clinical subjects.

- ▶ Can address almost any clinical question or issue, including screening test results or treatment outcomes, or natural history.
  - ▶ Most commonly used to describe clinical characteristics, such as signs and symptoms of disease or disease outcomes.
- 



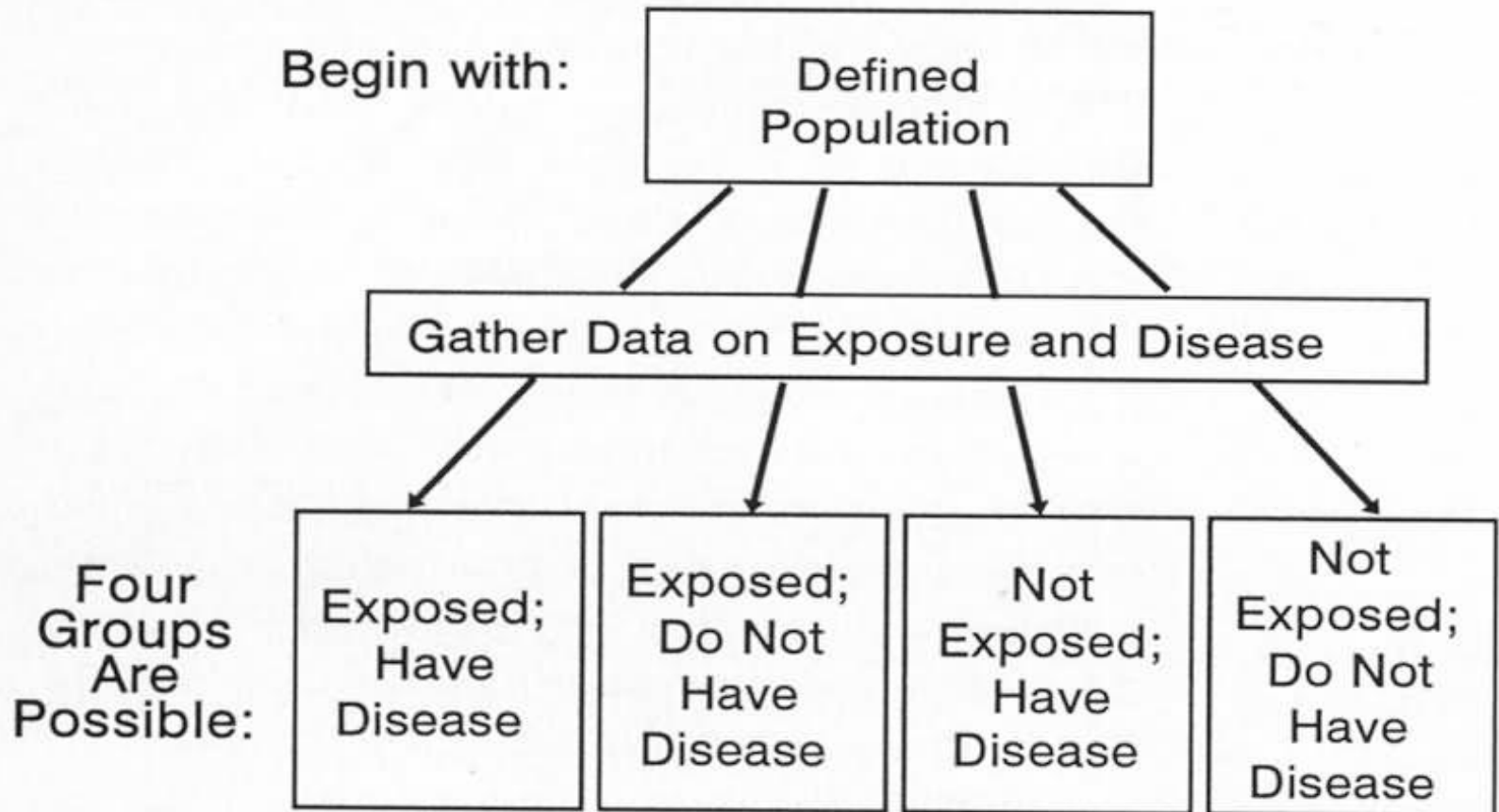
## EXAMPLE:

- ▶ Several children born with birth defects who were born to mothers who had taken thalidomide.

# Cross-sectional study

In such studies, both exposure and disease outcome are determined simultaneously.

# Cross-Sectional Study



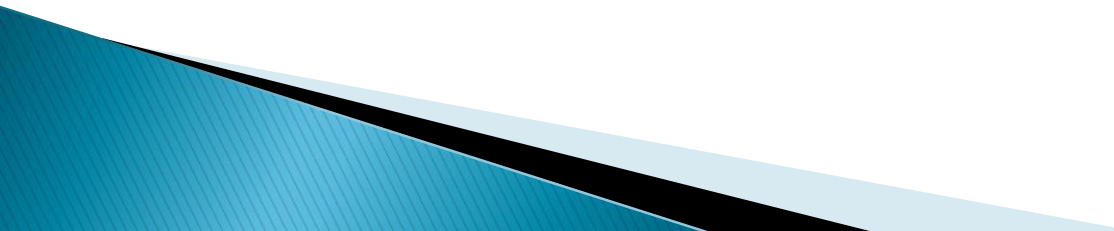
# Cross-Sectional Study

**Ask:** Do characteristics of the exposure factor coexist with the health problem?

Prevalence data; no risk statement


# Cross-Sectional Study

## Advantages:

- ▶ Gives general description or scope of problem
  - ▶ Useful in health service evaluation
  - ▶ Baseline for prospective study
  - ▶ Identify cases and controls for retrospective study
  - ▶ Get data all at once, so inexpensive
- 


# Cross-Sectional Study

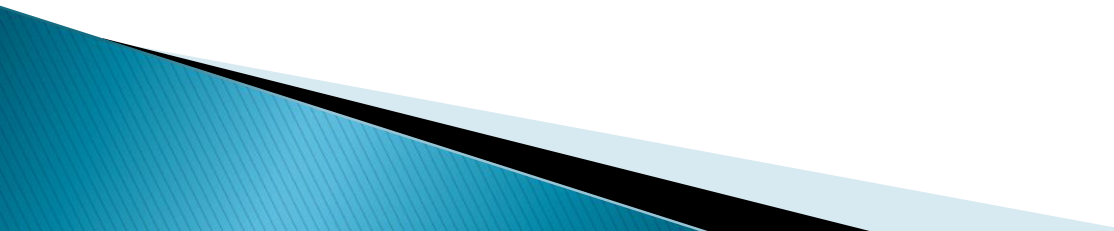
## Disadvantages:

- ▶ No calculation of risk
  - ▶ Temporal sequence unclear
  - ▶ Not good for rare disease
  - ▶ Selective survival can bias
  - ▶ Selective recall can bias
- 

# Retrospective or Case Control Study

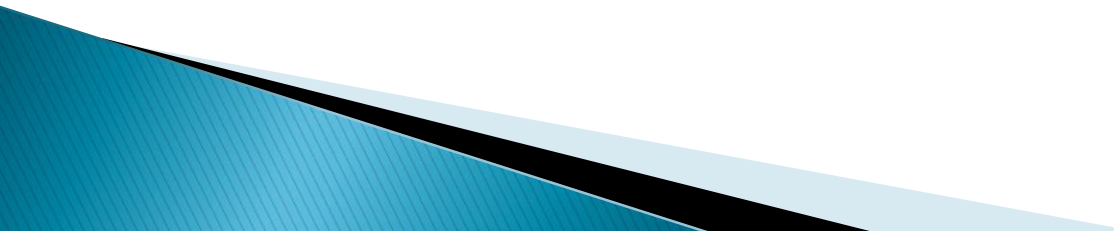
**An observational study in which diseased and un-diseased subjects are identified and then compared regarding specific characteristics to determine possible association or risk for the disease .**



- ▶ The case–control design is uniquely well suited to diseases with long induction period;
  - ▶ Uniquely suited to the study of rare diseases.
  - ▶ It shares the same logical framework of inference as the prospective study.
- 

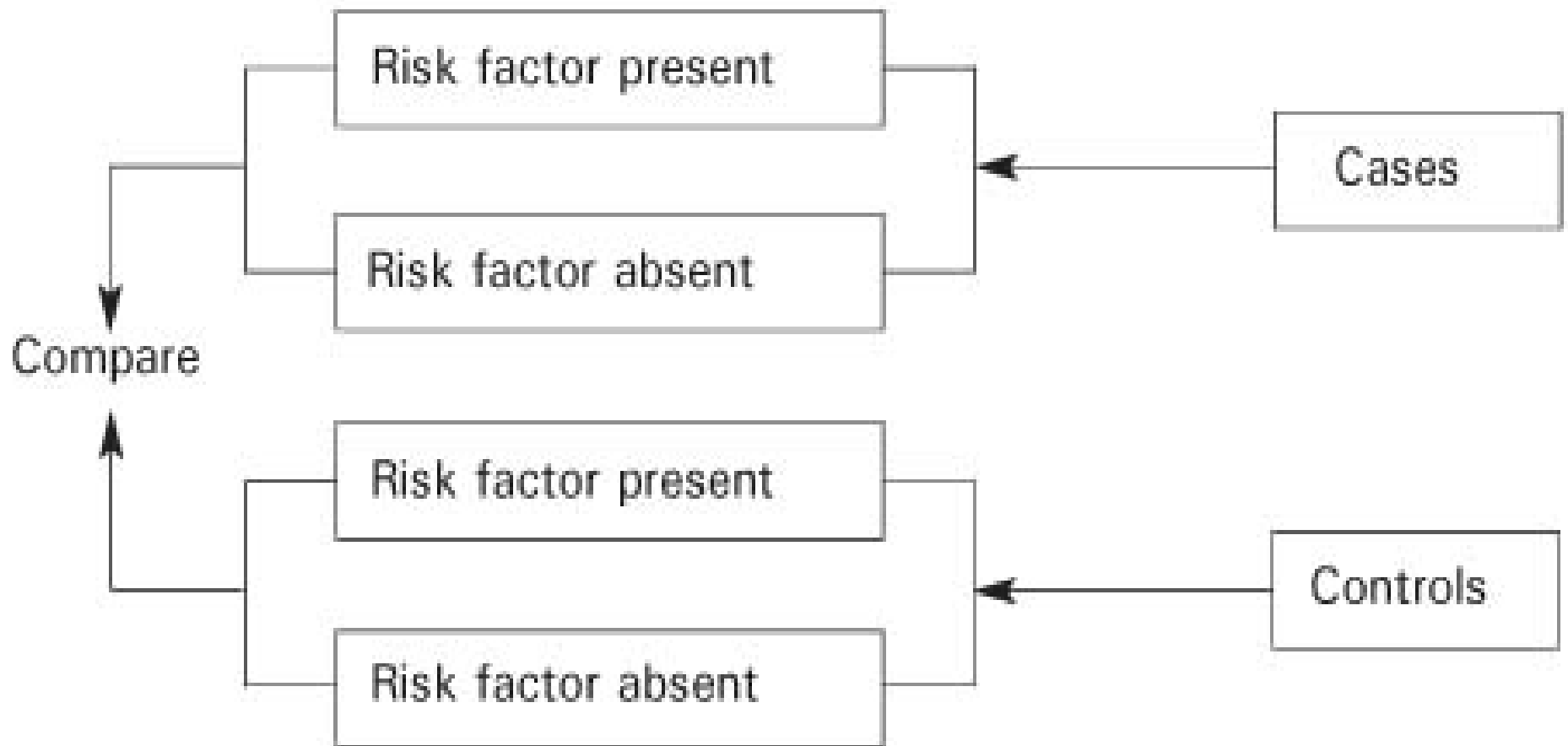


# Objectives:

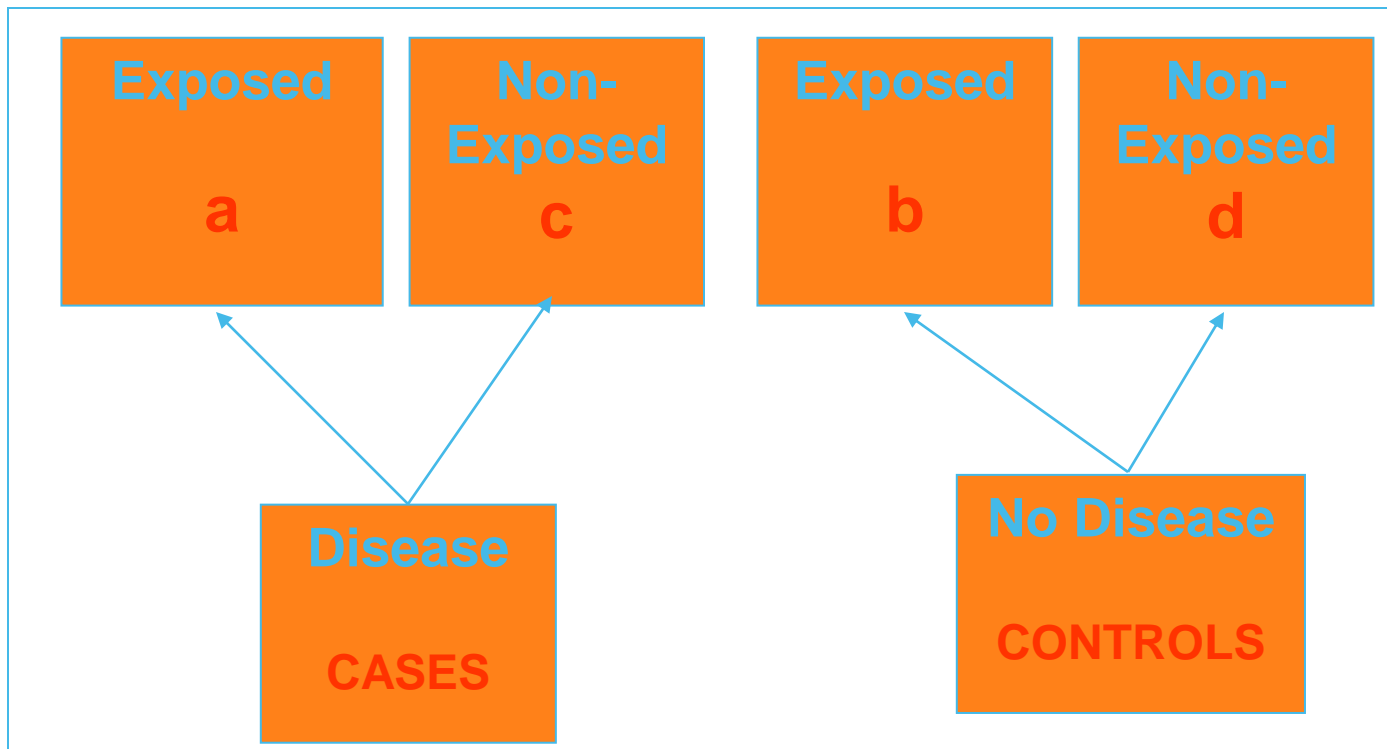
- ▶ To provide valid, reasonably precise, estimate of the strength of at least one hypothesised cause–effect relationship.
  - ▶ To evaluate several hypotheses – several different etiologic factors both as independent and interacting causes for a given disease.
- 

# Case control (retrospective )

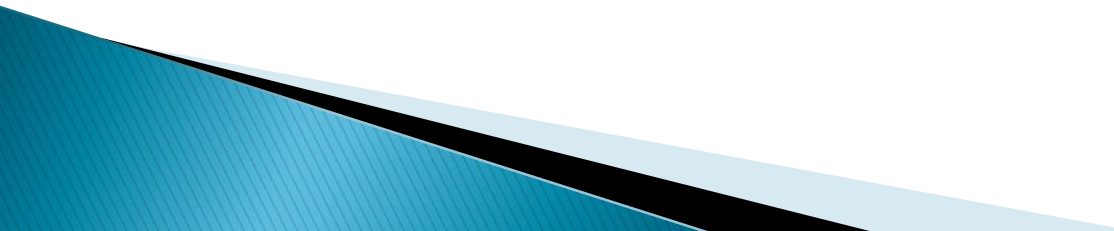
PAST ← ————— PRESENT  
(Retrospective study, looking backward)



# Retrospective or Case Control Studies

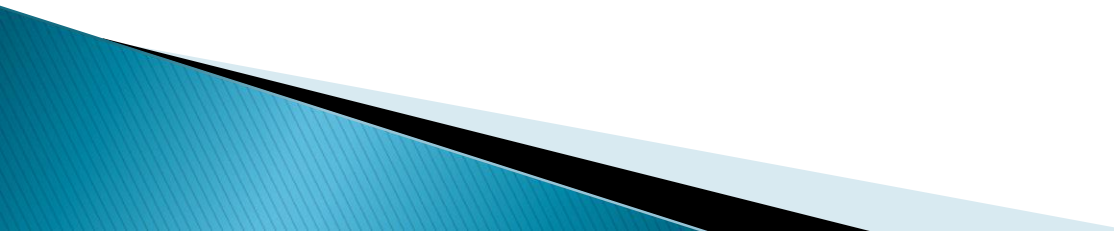


# Strengths:

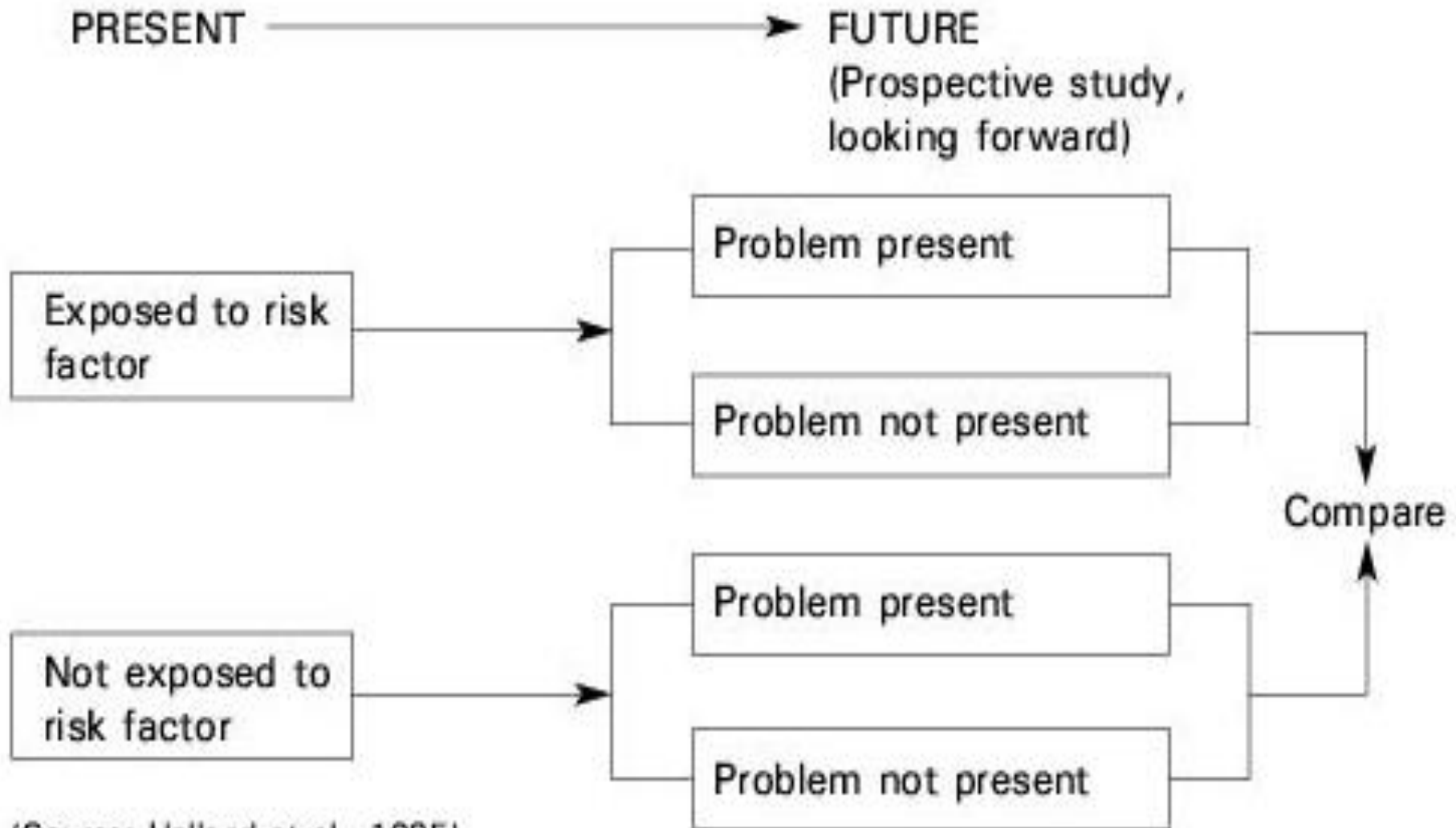
- ▶ Can simultaneously evaluate several causal hypotheses.
  - ▶ Permits evaluation of interaction (extent to which two or more factors modify the strength of one another).
  - ▶ Permits the evaluation and control of confounding.
  - ▶ If a population-based series of incident cases have been assembled, it is possible to estimate incidence rates.
- 

# Prospective or Cohort Study

In a cohort study, the investigator selects a group of exposed individuals and a group of non-exposed individuals, and follows up both the groups to compare the incidence of disease (or rate of death from the disease) in the two groups.

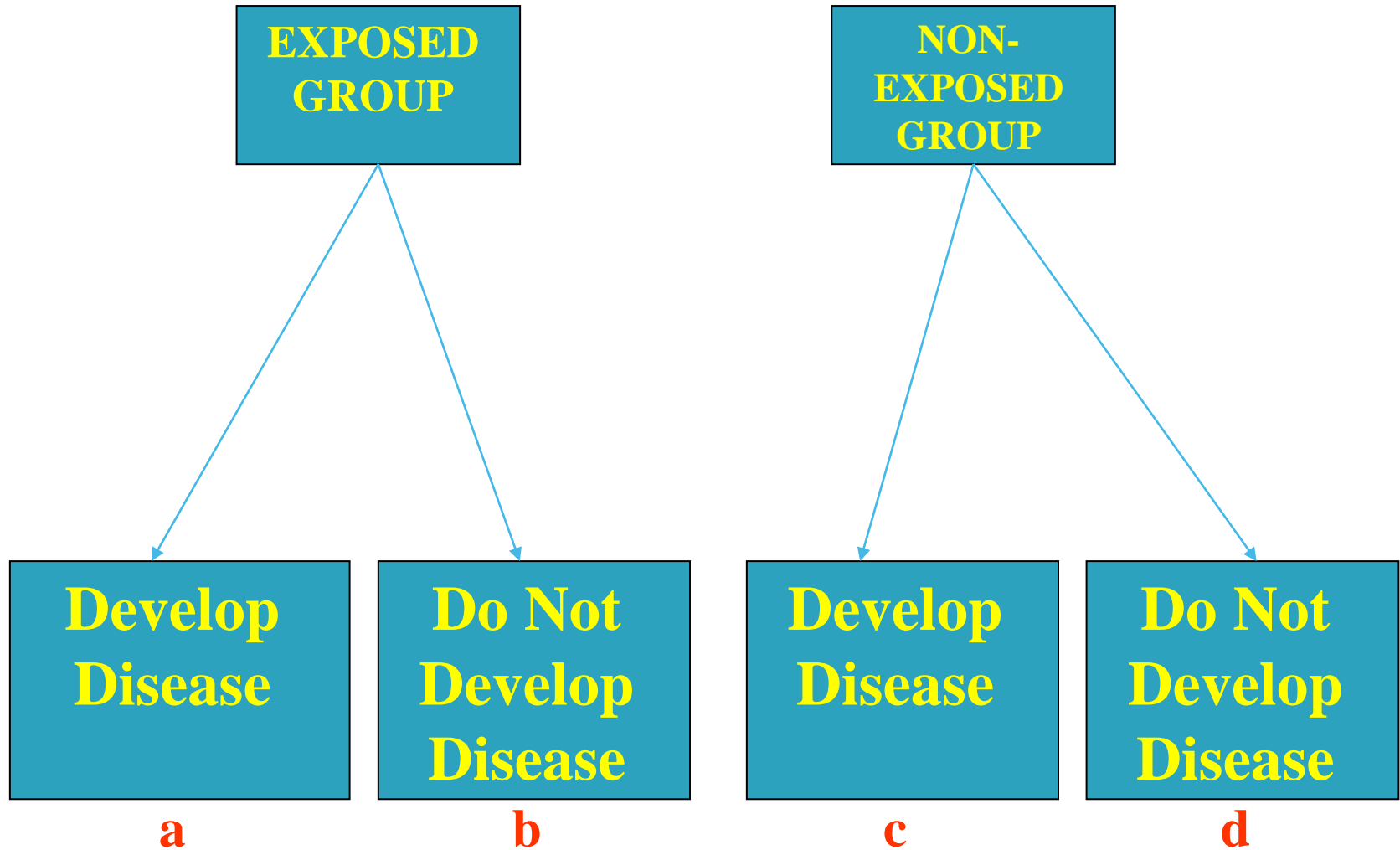


# Cohort studies (prospective)



(Source: Holland et al., 1985)

# Cohort Studies



# Experimental Studies

## Definition:

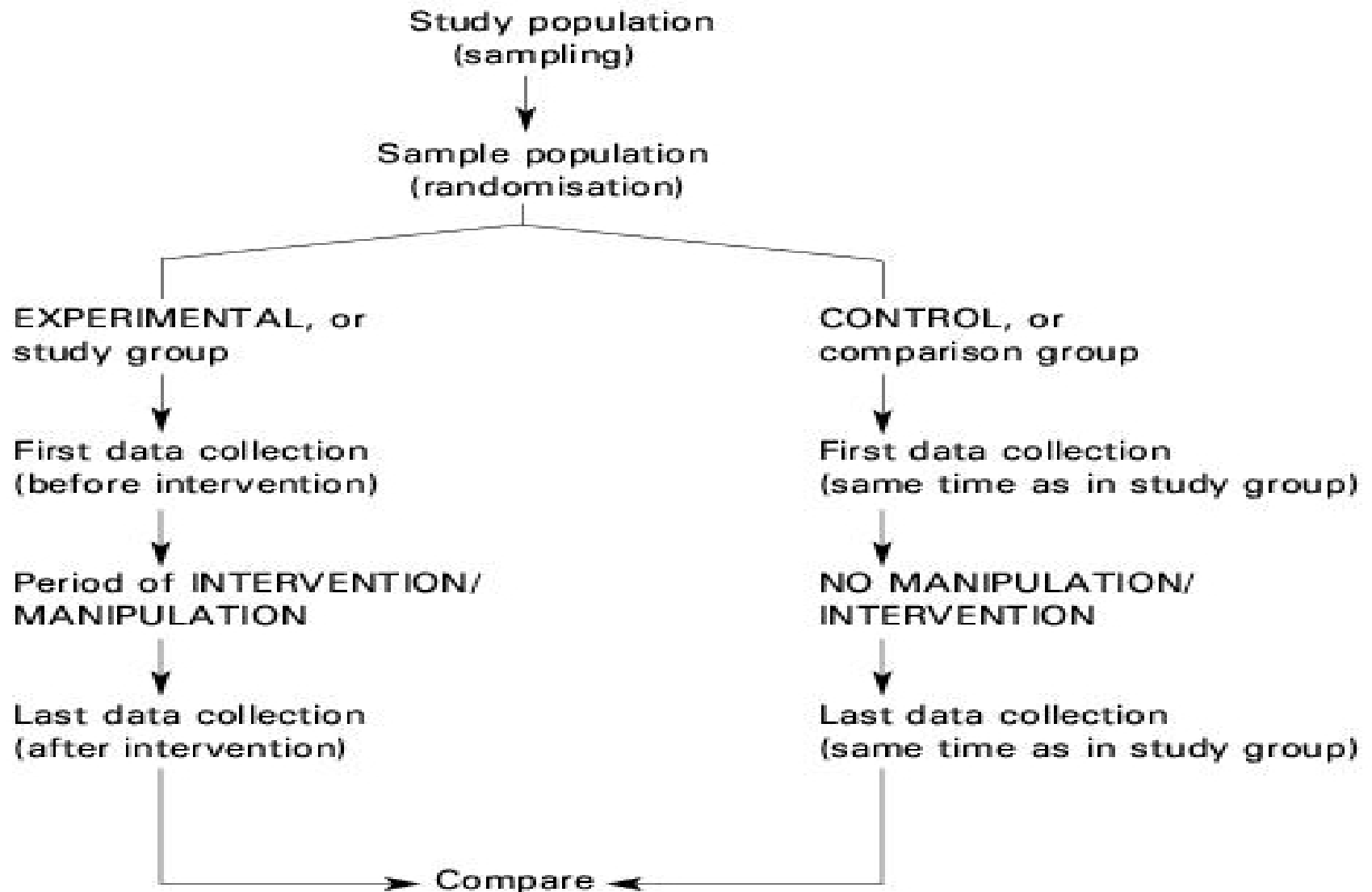
An intervention study is a research design in which the investigator manipulates a factor(s) and measures the subsequent outcome.

## Elements of a “complete” experiment:

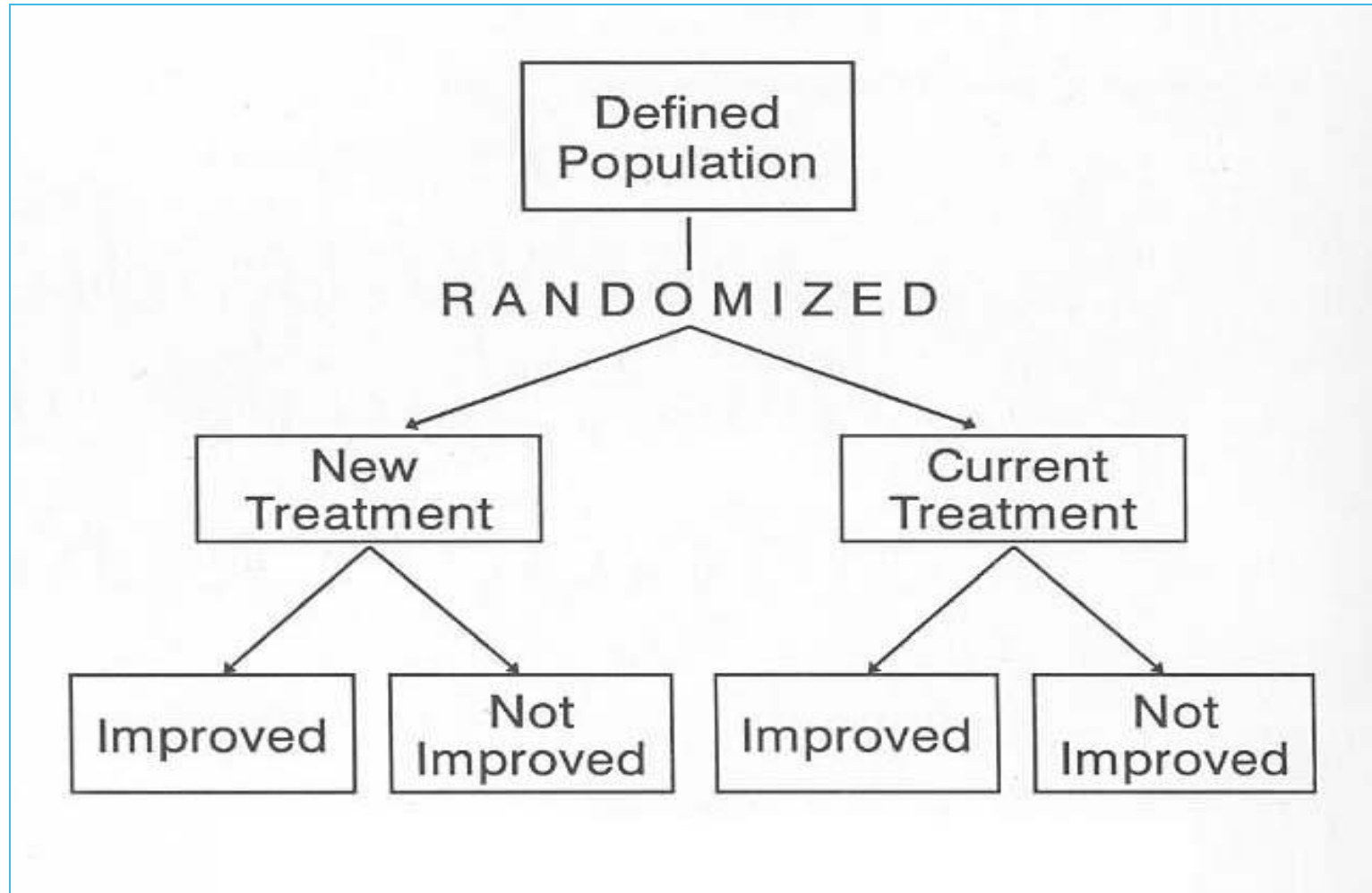
- ▶ Manipulation of independent variable:
- ▶ Use of a control group
- ▶ Ability to randomize subjects to treatment groups.



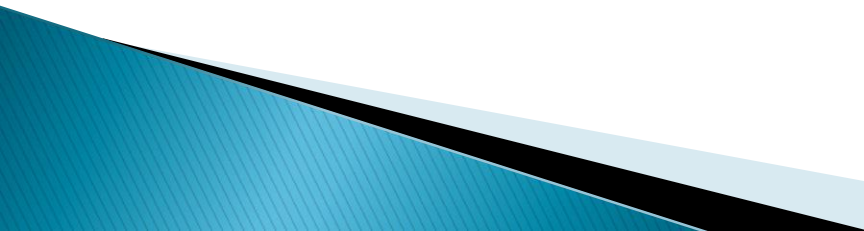
# Experimental studies



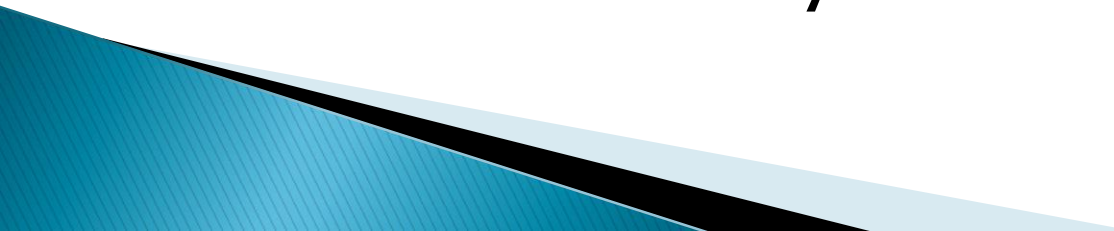
# Experimental Studies



# Advantages of experimental approach

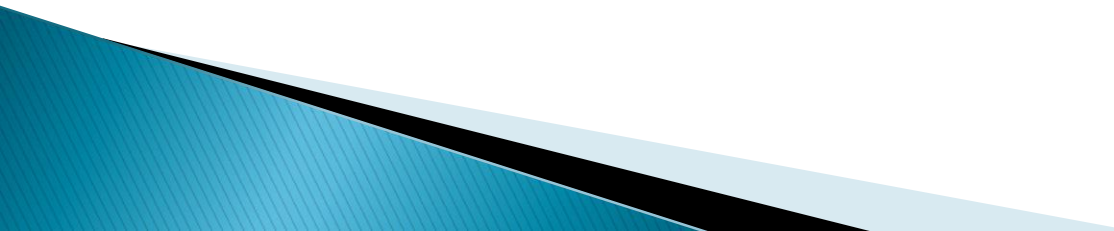
- ▶ Prospective direction
  - ▶ Ability to randomize subjects
  - ▶ Appropriate temporal sequence of cause and effect
  - ▶ Ability to control extraneous variables
  - ▶ “Best” evidence of causality
- 

# Disadvantages of experimental approach

- ▶ Expensive in time, personnel, facilities and cost.
  - ▶ Ethical constraints
  - ▶ Contrived situations
  - ▶ Impossible to control human behavior
  - ▶ External validity still uncertain
- 

# Experimental Studies

## Possible experimental outcomes:

- ▶ Symptoms
  - ▶ Laboratory test results
  - ▶ Morbidity
  - ▶ Mortality
- 

Any  
Question?



**THANK YOU**



# **The proposal**

**HOW TO WRITE A RESEARCH PROPOSAL**



# **OBJECTIVES**

**1- Interpret research types and design.**

**2- Define your idea in a proposal.**

**3- How to set the proposal.**

**4- To understand the different sections of the proposal.**

# PROPOSAL

## Consists of 4 chapters:

- 1) Introduction:
  - a) Introduction.
  - b) Statement of the problem.
  - c) Purpose of the study.
  - d) Significance of the study.
  - e) Basic assumptions.
  - f) Delimitation.
  - g) Hypothesis.
  - h) Definition of terms.
- 2) Literature review.
- 3) Material and methods.
- 4) References.

# 1) INTRODUCTION:

## a) Introduction:

- In this section the author(s) attempt to introduce the problems and questions, they addressed in conducting your experiment.
- After addressing previous studies, the authors make a statement of problem which encompasses the hypothesis of the study.

# INTRODUCTION:

## b) Statement of the problem:

- A problem statement is a clear concise description of the issue(s) that need(s) to be addressed by a problem solving team.
- It will be state in the form of the questions you want to answer, e.g.: Is there any relationship between the lumbar lordotic curve and pelvic inclination and can they affect on each other in MLBP patients?

# INTRODUCTION:

## c) Purpose of the study:

- The purposes of the study should explain the final conclusions that the research study hopes to reach.

Purposes should be written as statements.

e.g.: The purpose of the study was to evaluate the postural arrangement of the lumbar spine and the pelvis in the neutral standing position in chronic mechanical low back pain patients.

# INTRODUCTION:

## d) Significance of the study:

It provides details to the reader on how the study will contribute and who will benefit from it. It also includes an explanation of the work's importance as well as its potential benefits. It is sometimes called rationale.

- “What are the **benefits** or **advantages** of the study and what is **the difference** between you and others?”
- Determine the **specific contribution** of your thesis study to the **society** as well as to **the individual**?

# **INTRODUCTION:**

## **e) Basic assumptions:**

You will try to fix all other variables that may be affect your results, e.g.: **validity and reliability of the instrumentations, psychological status, medications, room temperature, ...etc.**

## **f) Delimitation:**

You will state the no. of subjects, their characteristics, instruments and intervention.

# INTRODUCTION:

## g) Hypothesis:

You will state that your dependent variables will be changed or not, usually the statement is non or null hypothesis. e.g.: the changes will not be significant.

There is no effect of dermal Iontophoresis of acetylcholine (Ach) on microcirculation changes in type 2 diabetes mellitus with peripheral neuropathy.

### Types of variables:

- Dependent variable
- Independent variable



## **Dependent variable**

Is the variable a researcher is interested in. The changes to the dependent variable are what the researcher is trying to measure with all their fancy techniques.

## **Independent variable**

is a variable believed to affect the dependent variable.  
This is the variable that the researcher, will manipulate to see if it makes the dependent variable change.

# Example of Variables in Scientific Experiments

- If a scientist conducts an experiment to test the theory that a vitamin could extend a person's life-expectancy, then:
- The independent variable is the amount of vitamin that is given to the subjects within the experiment. This is controlled by the experimenting scientist.
- The dependent variable, or the variable being affected by the independent variable, is life span.

# TYPES OF RESEARCH HYPOTHESES

## Alternative Hypothesis

The alternative hypothesis states that there is a relationship between the two variables being studied (one variable has an effect on the other).

- It states that the results are not due to chance and that they are significant in terms of supporting the theory being investigated.

## Null Hypothesis

The null hypothesis states that there is no relationship between the two variables being studied (one variable does not affect the other).

- It states results are due to chance and are not significant in terms of supporting the idea being investigated.

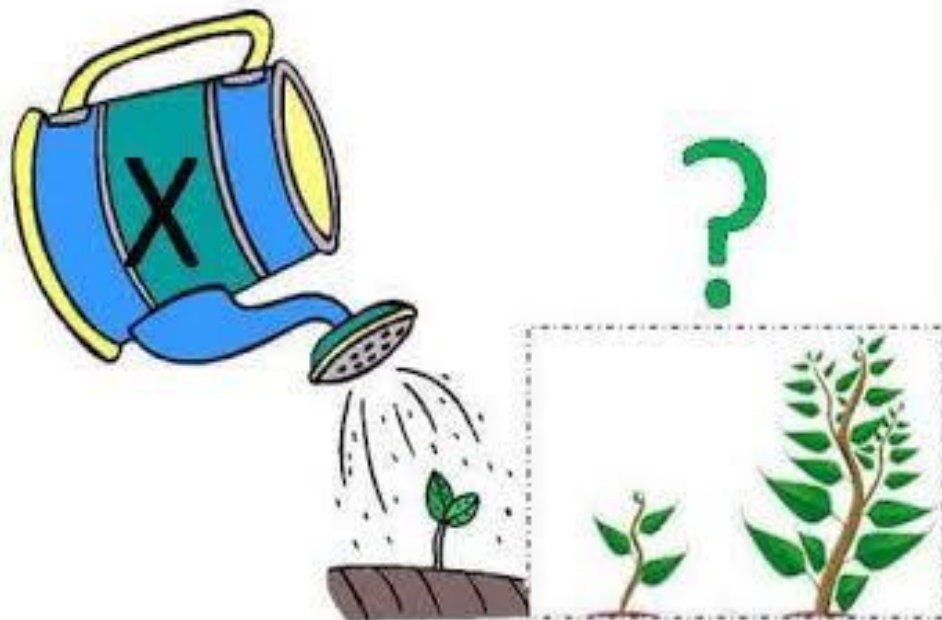


# Effect of Bio-fertilizer 'x' on Plant growth

[www.majordifferences.com](http://www.majordifferences.com)

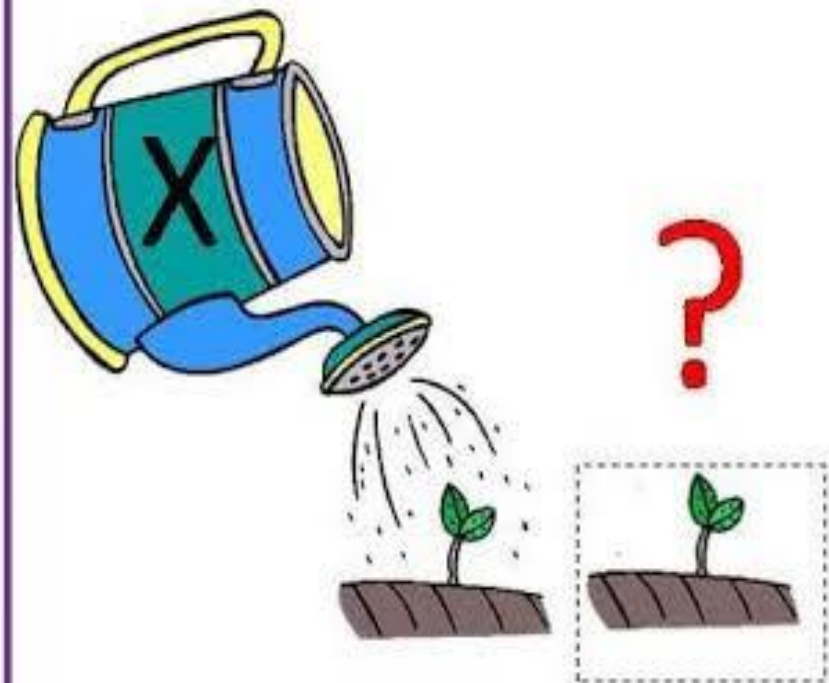
## Alternative Hypothesis

$H_1$ : Application of bio-fertilizer 'x' increase plant growth.



## Null Hypothesis

$H_0$ : Application of bio-fertilizer 'x' do not increase plant growth.



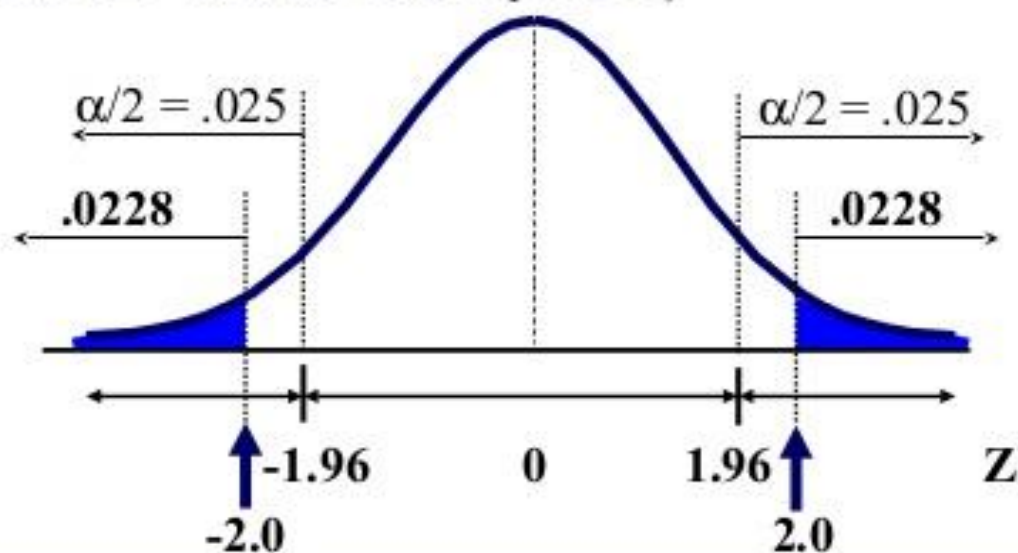


# Hypothesis Testing: $\sigma$ Known p-Value Approach

- Compare the p-value with  $\alpha$ 
  - If p-value  $< \alpha$ , reject  $H_0$
  - If p-value  $\geq \alpha$ , do not reject  $H_0$

Here: p-value = .0456  
 $\alpha = .05$

Since  $.0456 < .05$ , you  
reject the null  
hypothesis



## 2) LITERATURE REVIEW:

- It includes the current knowledge including substantive findings, as well as theoretical and methodological contributions to a particular topic.
- This looks at the breadth of literature relating to the themes in the article
- It may demonstrate holes in previous studies and looking for a wider body of knowledge relating to the topic.
- Demonstrates your understanding of the theoretical and research issues related to your research question.

### 3) Methods and Materials:

Everything about the conduction of the study is in this section

- **Subjects:** How many people/animals/? Their characteristics and how they were recruited etc....
- **Instruments.**
- **Procedure.**
- **Data processing and analysis.**
- How did the authors set up your experiment?
- **How many experimental groups did they have?**
- How did they measure the effect of the intervention?



## 4) References:

- List of all cited work in the specific reference style that is adopted by the journal.

What is a “citation”?

Author

Title

Title of the Journal

Volume #

Page #

Date

Publisher

= Citation



**Not a speeding ticket!!!!**

authors: last name, initials. (date).

Title of the article.

Luo, L., & Craik, F. I. M. (2008). Aging and memory: A cognitive approach. *Canadian Journal of Psychiatry*, 53(6), 346-53.

*Title of the journal in which  
the article appears,*

start page - end page.

volume # (issue #),

# COMMON MISTAKES IN PROPOSAL WRITING

- ❖ Failure to provide the **proper context** to frame the research question.
- ❖ Failure to **delimit** the boundary conditions for your research.
- ❖ Failure to **cite** landmark studies.
- ❖ Failure to accurately present **the theoretical and empirical contributions by other researchers.**
- ❖ Failure to **stay focused on the research question.**

- ❖ Failure to develop a **coherent** and persuasive **argument** for the proposed research.
- ❖ Too much detail on **minor issues**, but **not enough detail on major issues**.
- ❖ Too much rambling -- going "all over the map" without a clear sense of direction. (**The best proposals move forward with ease and grace like a seamless river.**)

- ❖ Too many citation lapses and **incorrect references**.
- ❖ Too long or too short.
- ❖ Slopping writing. (**weak or watery**).
- ❖ Failing to follow the APA style.
- ❑ It is described in the style guide of the American Psychological Association (APA).
- ❑ **style** and format for academic documents such as scholarly journal articles and books.

# Assignment

- Each one will choose an article that addresses an experimental study (in any field of PT, e.g. ortho, neuro, ...).
- Please give the full citation for article.
- Answer the questions on the following slides.
- The answers should not take more than 5 pages

## The questions:

- Why the study was done? i.e. What is (are) the question(s)
- What is (are) the hypothesis(es) of the study?
- Determine the variables?
- What is the relevance of this study to clinical practice/real world?
- How did the author decide on the sample/subjects of the study and their characteristics?
- What are the outcome measures for the study?
- Did the results answer the question(s) for the study?
- Did the authors make proper conclusions from the results.

# Literature Review

---

**Dr. Mohammed Essam**

Lecturer of Physical Therapy  
South Valley University



- **Usually Research consists of:**

1. Asking a question that nobody has asked before.
2. Doing the necessary work to find the answer.
3. Communicating the knowledge you have acquired to a larger audience.

# A literature review or survey

The aim of a literature review is to show your  
reader (e.g. your supervisor) that you have read  
and that you have a good grasp of the main  
published work concerning a particular topic or  
question in your field.

# Literature survey

## The literature review guidelines:

---

- 1) **compare** and **contrast** different authors' views on an issue.
- 2) Group authors who draw **similar conclusions**.
- 3) **Criticize** aspects of methodology.
- 4) Note areas in which **authors are in disagreement**.

5) Highlight **exemplary studies**.

6) Highlight **gaps in research**.

---

7) Show how your study **relates to previous studies**.

8) Show how your study **relates to the literature in general**.

9) **Conclude by summarizing** what the literature says.

# The general purposes of the review are to:

- 1) Help you **define and limit the problem** you are working on.
- 2) Help you place your study in an **historical perspective**.
- 3) Help you avoid **unnecessary duplication**.
- 4) Help you evaluate **promising research methods**.
- 5) Help you **relate your findings to previous knowledge** and **suggest further research**.

If you make a good literature review you will have the following advantages:

---

- 1) It shows that you do **not only understand** what you have done, **but you understand what others have done** related to your subject in a broader context.
- 2) It shows that you **are intelligent enough to evaluate the quality of the other research** work done on the subject.

3) It gives you the opportunity to tell how your research is related to previous work done by others on the subject.

---

4) It tells the reader if you are simply going to duplicate others' work to gain a better understanding, or whether your focus is to improve upon others' work or perhaps combine the methodology of two or more existing approaches for solving a problem.

# Writing a Literature Survey

- **BE A HUNTER!** Go online and search for **articles, books and papers** related to your subject.

---

- **Be creative and persistent** in your keyword search until you **hunt down good references** or examples.
- Ask your **supervisor for recommendations** (but **don't totally rely** only on these!).
- First record the citation on your list of references, **using the APA style**, (the style guide of the American Psychological Association).



- When you read some literature that is not very useful, **do not include it on your list of references.**
- In each document, **identify the approach** (es)/method(s) for solving problem(s), and compare this/these with what you already know.
- Identify which **approaches** and/or **methods** you will use and omit in your research.

## Types of Knowledge that Research Contributes

1. **Description:** Results of research can describe natural or social phenomenon, such as its form, structure, activity, change over time, relationship to other phenomena.
2. **Prediction:** Prediction research is intended to predict a phenomenon that will occur at time Y from information at an earlier time X. It could also be to predict parameter A (dependent variable) based on parameter B (independent variable).

3. **Improvement:** This type of research is **mainly concerned with the effectiveness of intervention.** The research approach includes experimental design and evaluation research. It is aimed at providing improvement on an already established research or fact.

4. **Explanation:** This type of research subsumes the other three:

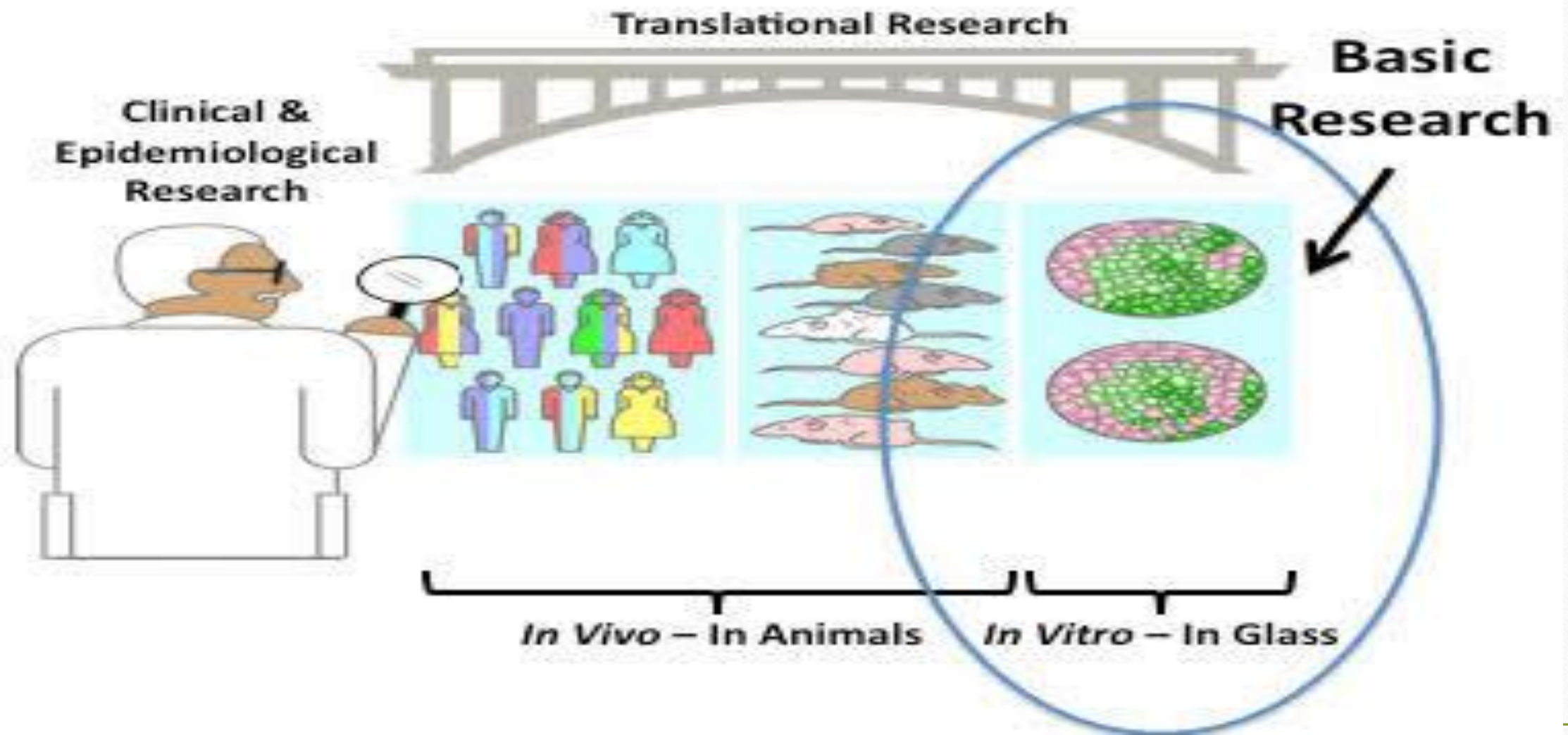
the researchers are able to **explain an educational phenomenon,** it means that they can **describe,** can **predict its consequences,** and **know how to intervene to change those consequences.**

# What are the Purposes of Research?

---

**1- Basic Research:** The purpose of this research is to **understand and explain,** This type of research takes the form of a theory that explains the phenomenon under investigation to give its contribution to knowledge. **This research is more descriptive in nature exploring what, why and how questions.**

# Types of Research



**2- Applied Research:** The purpose of this research is to help **people understand the nature of human problems** so that human beings can more **effectively control** their environment. In other words, this type of research pursues **potential solutions to human and societal problems.** This research is more prescriptive in **nature, focusing on how questions.**



Basic Research



Theoretical

Knowledge expansion

Applied Research



Practical

Betterment of humans

**3- Evaluation Research: (summative and formative):** Evaluation research studies the processes and outcomes aimed at attempted solution. The purpose of **formative** research is to **improve human intervention within specific conditions**, such as activities, time, and groups of people; the purpose of summative evaluation is to judge the effectiveness of a program, policy, or product.



# METHODS

DEFINITION

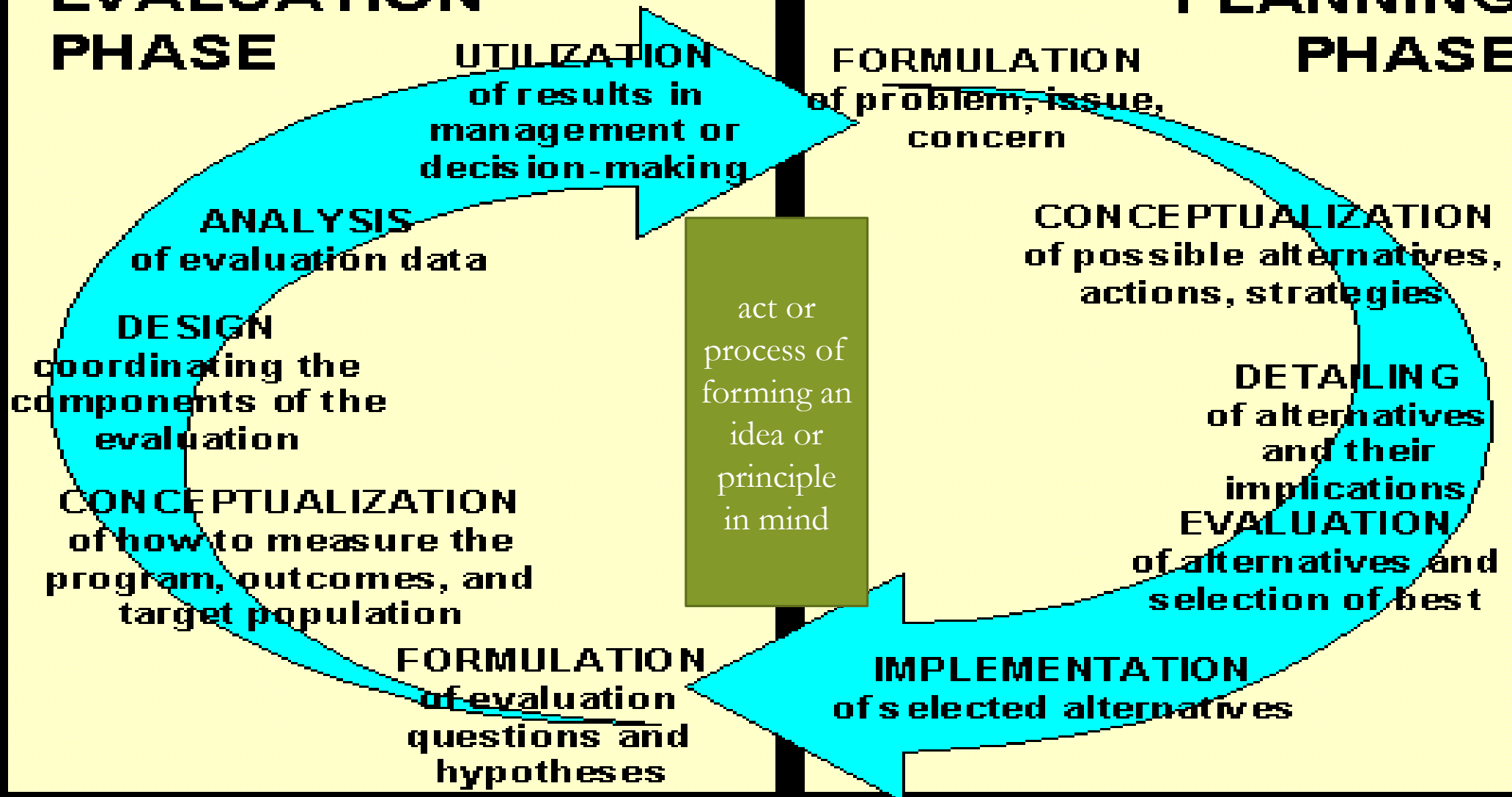
EXAMPLES



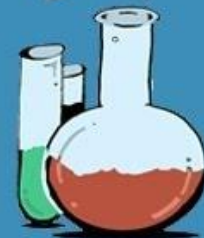
**EVALUATION  
RESEARCH**

# EVALUATION PHASE

# PLANNING PHASE



# WHAT IS ACTION RESEARCH?



**4- Action Research:** aims at **solving specific problems**

within a program, organization, or community. **Patton**

**(1990)** described that design and data collection in action

research tend to be more **informal**, and the people in the

situation are directly involved in **gathering information** and

**studying themselves.**

**For example:** Individual action research involves working independently on a **project, such as an elementary school teacher conducting her own, in-class research project with her students.** ... Teams of staff members would work together using school-wide action research.

# Action research

**Planning**

identifying  
informing  
organising

**Acting**

trailing  
collecting  
questioning

**Observing**

evaluating  
implementing  
revisiting

**Reflecting**

analysing  
reporting  
sharing

# Research and Development

---

Let's begin with a question that has an obvious answer. What's the difference between a wall phone (circa 1907) and an iPhone 5? Their **functions**, **size** and their **composition** are very different.



≠



THANK YOU





# DATA COLLECTION METHODS

**Dr. Mohammed Essam**

Lecturer of Physical Therapy for Integumentary System  
Disorders and Burn

South Valley University



# WHAT IS DATA?????

**Data** are the **set of values** of qualitative or quantitative variables about one or more persons or objects.

- ▶ Data are **simply units** of information.
- ▶ Data are measured, collected, reported, analyzed, and used to create data visualizations such as graphs, tables or Images.

**You can have data without information, but you cannot have information without data.**

Daniel Keys Moran

# 1- Quantitative Data (Numerical)

► Data refers to measurable observations.

- **Quantitative** – based on numbers – 56% of 18 year olds drink alcohol at least four times a week - doesn't tell you why, when, how.

► Examples-

- Height of 1<sup>st</sup> graders
- Weight of sumo wrestlers
- Duration of red lights
- Age of Olympians
- Distance of planets
- Money in 401k plans
- Temperature of coffee (200 F)



## 2- Qualitative Data (categorical)

▶ **Qualitative data** is the data that can be arranged into **categories** based on **physical traits, gender, colors** or anything that **does not have a number** associated with it.

▶ Qualitative-involves **more details** tells you *why, when and how!*

▶ **Examples-**

- Happiness rating
- Gender
- Pass/Fail
- Eye Color
- Interview transcript
- Categories of plants
- Descriptive temperature of coffee ("very hot")

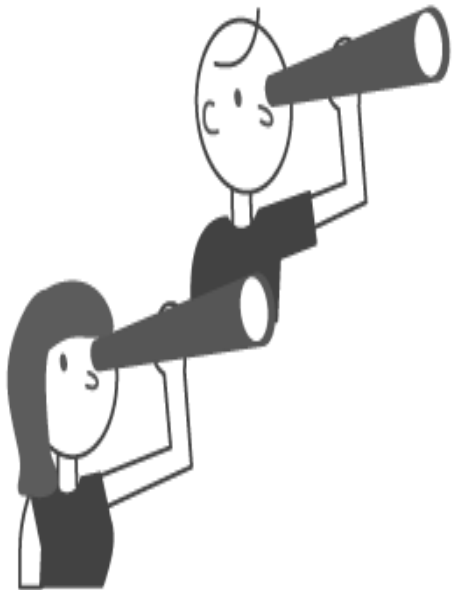


# What is Data Collection?

- It is the process by which the researcher collects the information needed to answer the research problem (question).
- The task of data collection begins **after** a research problem (question) has been defined.



In collecting the data, **the researcher must**  
**decide:**



- **Which** data is to collect?
- **How** to collect the Data?
- **Who** will collect the Data?
- **When** to collect the Data?



# The Purpose of Data Collection

- The purpose of data collection is-
  - ✓ to obtain information
  - ✓ to keep on record
  - ✓ to make decisions about important issues,
  - ✓ to pass information on to others





# Methods of Data Collection

According data source divided into:

➤ PRIMARY DATA:

Primary data are those which are collected for **the first time** and are **original** in character.

➤ SECONDARY DATA:

Secondary data are those which have **already** been collected-by **someone else**.



# Primary Data v/s Secondary Data

## Primary data

- Real time
- Sure about the sources
- Can answer research question.
- Cost and time
- Can avoid bias
- More flexible

## Secondary data

- Past data
- Not sure about sources
- Refining the research problem
- Cheap and no time
- Bias can't be ruled out
- Less flexible

# Methods of Collecting Primary Data

**Primary Data  
collected  
through:**

- **Observation.**
- **Surveys.**
- **Interviews.**
- **Questionnaires.**
- **Schedules.**

# 1. Observation Method



**Observation method** is a method under which data from the field is collected with the help of observation by the observer or by personally going to the field.



# Steps For An Effective Observation

**Determine what needs to be observed**



**Select participants**

Random/Selected



**Conduct the observation**

(venue, duration, recording materials, take photographs )



**Compile data collected**



**Analyze and interpret data collected**



# Types of Observation Methods

## 1- Structured Observation:

When the observation is characterized by a careful definition of the units to be observed (**predefined**), the **style of recording** the observed information, **standardized conditions** of observation and the **selection of related data** of observation.

## 2- Unstructured Observation:

When it takes place without the above characteristics. (Not predefined).

### 3- Participant Observation:

When the observer is **member** of the group which he is observing.

### 4- Non-Participant Observation:

When the observer **is not the member** of the group which he is observing.

observer is observing people **without giving** any information to them.

## 5- Uncontrolled Observation:

When the observation takes place in **natural condition** i.e., uncontrolled observation. It is done to get spontaneous picture of life and persons.

## 6- Controlled Observation:

When observation takes place according to **pre-arranged plans**, with experimental procedure then it is controlled observation generally done in laboratory under controlled condition.



# Advantages of observation Method

Produces Large quantities of data.

All data obtained from observations are usable.

The observation technique can be stopped or begun at any time.

Relative Inexpensive

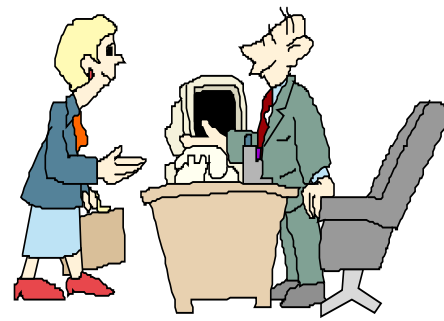
## Disadvantages of observation Method

Interviewing selected subjects may provide more information, economically, than waiting for the spontaneous occurrence of the situation.

Extensive Training is needed.

Limited information.

## 2. SURVEY Method



A 'survey' is a technique of gathering information by **questioning** those individuals who are the object of the research belong to a representative sample, through **standardized** or **questioning procedure**.

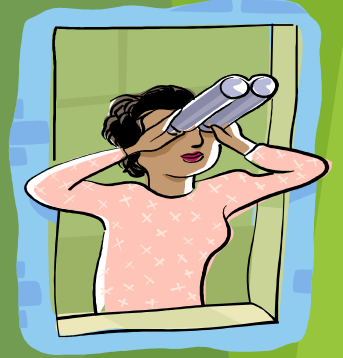
Aiming of studying the **relationship** among the variables and/or collecting information that probably **describe** the whole population.

One of the widely used research design  
to collect data is

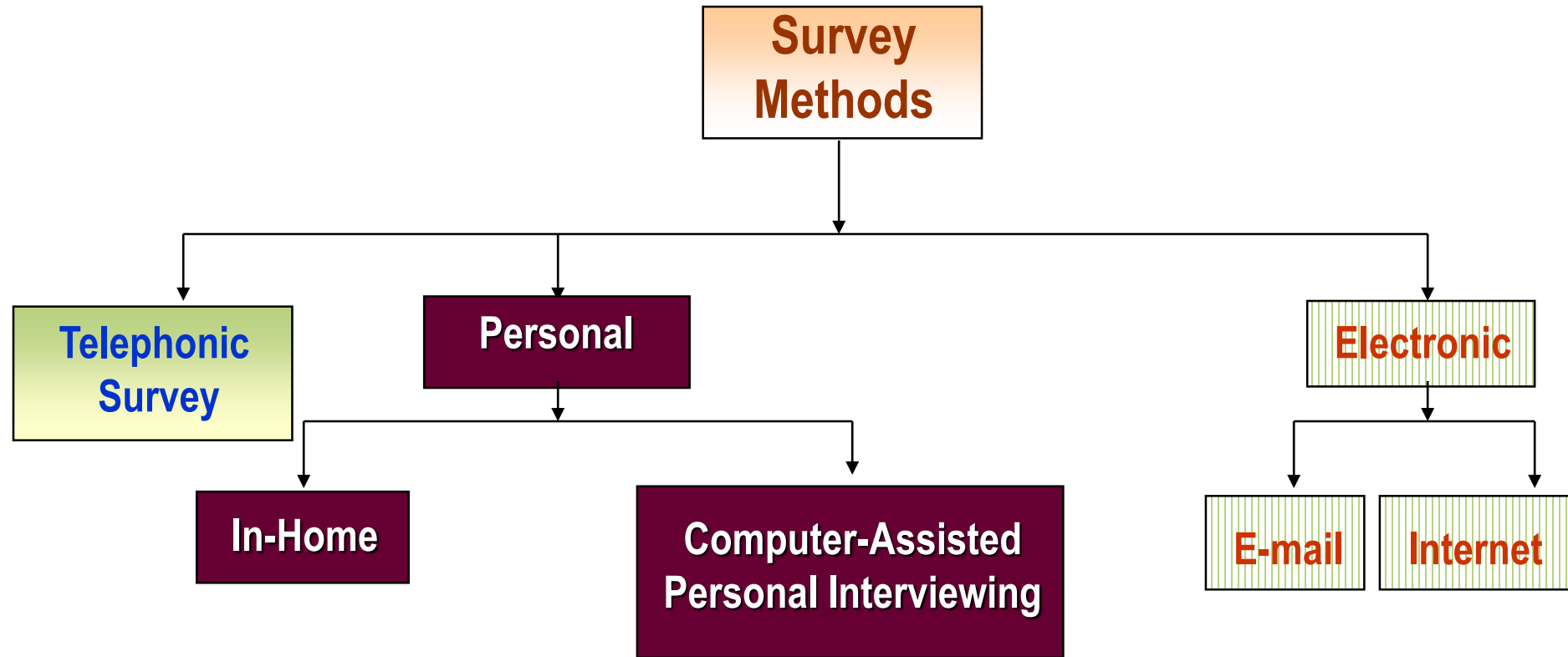
# SURVEYS

# How to collect Primary information through survey

- ▶ A researcher can collect information  
Either by observation or by asking.
- ▶ When he/she asks for information, we say that he/she is conducting a survey.



There may be different ways to conduct surveys...



# 3. Interview Method



- The Interview Method of collecting data involves presentation of **oral-verbal stimuli** and reply in terms of **oral- verbal responses**.
- Where the questions are asked **personally** directly to the respondent.
- Interviewer asks questions to respondent. (which are aimed to get information required for study)



# Steps For An Effective Interview

**Prepare interview schedule**



**Select subjects/ key**



**Respondent Conduct the  
interview**



**Analyze and interpret data collected from the  
interview**





# Types of Interview Methods

## 1- Structured Interviews:

In this case, a set of **predecided** questions are there.

## 2- Unstructured Interviews:

In this case, we **don't follow** a system of pre-determined questions.

## 3- Focused Group Interview:

- ▶ **Unstructured** and **Free** flowing.
- ▶ Focus Group has **one Moderator**.
- ▶ Moderator maintains **control** and **focuses** discussion.
- ▶ It involves **6 to 10** people.
- ▶ Group interview start with **broad** topic and **focus** in on **specific** issues.
- ▶ Similar lifestyles and experiences.
- ▶ Generate **discussion** and **interaction**.
- ▶ **Listens** to what people have to say.
- ▶ **Everyone** gets a **chance** to speak.

A research method that brings together a small group of consumers to discuss the product or advertising, under the guidance of a trained interviewer.



#### 4- Qualitative and quantitative Interviews :

It is divided on the **basis of subject matter** i.e., whether **qualitative** or **quantitative**.

#### 5- Individual Interviews :

Interviewer meets a **single person** and interviews him.

#### 6- Selection Interviews :

Done for **selection of people** for certain Jobs or according to certain criteria.

# Advantages of Interview Method

More information at greater **depth** can be obtained

**Resistance** may be overcome by a skilled interviewer

**Personal information** can be obtained

## disadvantages of Interview Method

It is an expensive Method

Interviewer bias

Respondent bias

Time consuming

# 4. Questionnaires

- The term “questionnaire” refers to an **instrument** for the collection of data, usually in **written form**, consisting of **open/closed questions** and other enquiries requiring a response from subjects.
- A Questionnaire is **sent** ( by **post** or by **mail** ) to the persons concerned with a request to answer the questions and return the Questionnaire.
- A Questionnaire consists of a number of **questions** printed in a **definite order** on a form.



# Steps For An Effective Questionnaire

## **Prepare questions**

(Formulate & choose types of questions, order them, write instructions, make copies)



## **Select your respondents** Random/Selected



## **Administer the questionnaire** (date, venue, time )



## **Tabulate data collected**



## **Analyze and interpret data collected**





# Types of Questionnaire Methods

## 1- Open-ended questions:

This gives the respondents the **ability to respond in their own words.**

## 2- Close-ended or fixed alternative questions:

This allows the respondents to **choose one of the given alternatives.**

**Types**:- **Dichotomous** questions and **Multiple** Questions.

# Essentials of Good Questionnaire

- Should be **short** and **simple**
- Follow a **sequence** of questions from **easy to difficult** one
- **Technical terms** should be **avoided**
- Should provide **adequate space for answers** in questionnaire
- **Directions** regarding filling of questionnaire should be given
- Physical Appearance – Quality of paper, Color.
- **Sequence** must be **clear**



# Advantages of questionnaire Method

**Low cost** –even when the universe is large and is widespread

Free from interviewer **bias**

Respondents have adequate **time** to think through the answers.

Respondents **who are not easily approachable**, can also be reached conveniently.

**Large samples** can be used

# Disadvantages of questionnaire Method

Time consuming

The respondents need to be **educated** and **cooperative**

This method is **slow**

Possibility of **unclear** replies.

# 5.Schedules

- Very **similar** to **Questionnaire** method.
- The main **difference** is that a schedule is **filled by the enumerator**, who is specially appointed for the purpose.
- Enumerator **goes to** the respondents, **asks** them the questions from the Questionnaire in the order listed, and **records** the responses in the space provided.
- Enumerator must be **trained** in administering the schedule.



# Questionnaire Vs. Schedule

## Questionnaire

- Q generally send to through **mail** and no **further assistance** from sender.
- Q is **cheaper** method.
- **Non response** is **high**.
- In questionnaire, it is **not confirmed** that expected respondent have filled the answers.

## Schedule

- Schedule is filled by the **enumerator** or **research worker**.
- **Costly** requires field workers.
- **Non response** is **low**.
- In schedule **identity** of person is known.

# Secondary Data Collection Methods

- Data gathered and recorded by **someone else**.
- Secondary data is data that has been **collected for another purpose**.
- It involves **less cost, time and effort**.
- Secondary data is data that is being **reused**. Usually in a **different context**.

# Sources of secondary data collection

## 1- Internal sources:

**Internal sources are usually for marketing application-**

- ▶ Sales Records
- ▶ Marketing Activity
- ▶ Cost Information
- ▶ Distributor reports and feedback
- ▶ Customer feedback



## **2- External sources:**

- ▶ Journals
- ▶ Books
- ▶ Magazines
- ▶ Newspaper
- ▶ Libraries
- ▶ The Internet

# **Selection of proper Method for collection of Data**

- ▶ Nature ,Scope and object of inquiry
- ▶ Availability of Funds
- ▶ Time Factor
- ▶ Accuracy Required

# Advantages of secondary data Method

- Ease of Access
- Low Cost to Acquire
- Clarification of Research Question
- May Answer Research Question

# Disadvantages of secondary data

## Method

- ❑ Quality of Research
- ❑ Not Specific to Researcher's Needs
- ❑ Incomplete Information
- ❑ Not Timely

THANK YOU ALL

To be Continued ....

# **Establishing the Validity and Reliability of a Research Instrument**

**Dr. Mohammed Essam**

**Lecturer of Physical Therapy**

**South Valley University**

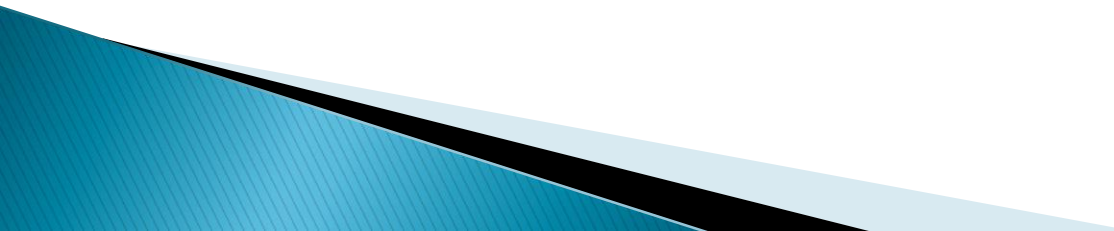
# A- The concept of validity

Validity is the degree to which the researcher has measured what he has set out to measure.

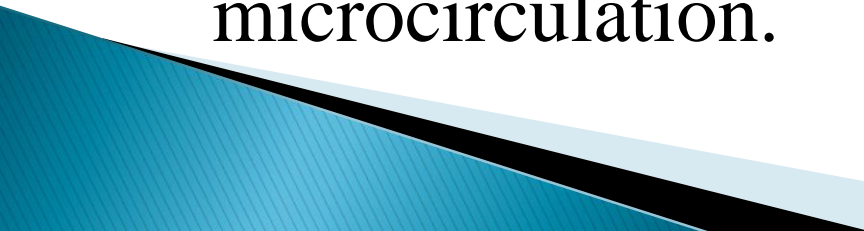
- The common definition of validity is epitomized by the question: **Are we measuring what we think we are measuring?**
- The instrument is **measuring what it was designed or supposed to measure.**

# Examples

## Evaluation equipment

- ❑ Blood samples for measurement Lipid profile
  - ❑ GENU. for measurement ROM
  - ❑ X ray for measurement Bone trauma
  - ❑ MRI for measurement Disc lesion
- 



- ❑ pulmonary fun. for measurement Lung volumes.
  - ❑ NCV for measurement Nerve injury.
  - ❑ Standard pulsed-wave Doppler velocimetry for measurement of blood flow velocimetry.
  - ❑ Laser Doppler qualification for measurement of microcirculation.
- 

# The four types of validity

- 1- **Construct validity**: Does the test measure the concept that it's intended to measure?
- 2- **Content validity**: Is the test fully representative of what it aims to measure?
- 3- **Face validity**: Does the content of the test appear to be suitable to its aims? subjective assessment
- 4- **Criterion validity**: Do the results correspond to a different test of the same thing?


# 1- Construct validity

- Construct validity: Does **the test measure** the concept that **it's intended to measure**?
- Construct validity is about ensuring that **the method of measurement matches the construct you want to measure.**

## EX:-

- We can measure **depression** based on a collection of symptoms and indicators, such as **low self confidence** and **low energy levels.**

## 2- Content validity

- Content validity: Is the **test fully representative** of what it **aims to measure**?
  - Content validity assesses whether a test is representative of **all aspects of the construct**.
  - To produce valid results, the content of a test, survey or **measurement method must cover all relevant parts of the subject it aims to measure**.
- 

# 3- Face validity

- Face validity: Does **the content of the test** appear to **be suitable to its aims?**
- It's similar to content validity, but face validity is a more informal and **subjective assessment**.
- As face validity is **a subjective measure**, it's often considered the **weakest form of validity**.


**EX:-**

- You review the survey items, which **ask questions** about every meal of the day and snacks eaten in between for every day of the **week**.

## 4- Criterion validity

- Criterion validity: Do the results correspond to a different test of the same thing?
- Criterion validity evaluates how closely the results of your test correspond to the results of a different test.
- To evaluate criterion validity, you calculate the correlation between the results of your measurement and the results of the criterion measurement.

## B- The concept of reliability


- The greater the degree of consistency and stability in an instrument, the greater its reliability.
  - Therefore, reliability is the degree of accuracy or precision in the measurements made by a research instrument.
  - The lower the degree of error in an instrument, the higher the degree of reliability.
- 

# Factors affecting the reliability of a research instrument

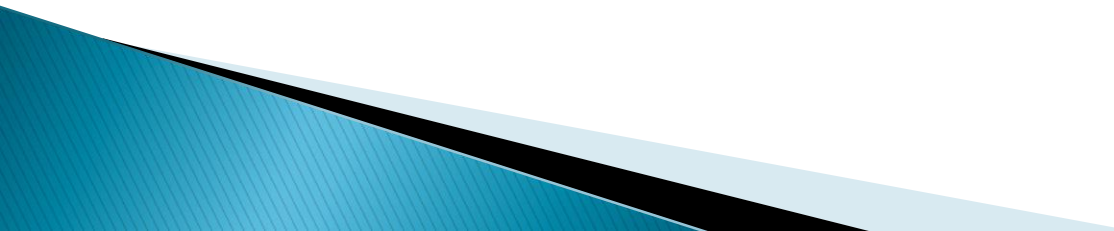
In the social sciences it is impossible to have a research tool which is **100 % accurate**, not only because a research instrument cannot be so, but also because it is impossible to control the factors affecting reliability.

- 1) **The wording of questions** – A slight ambiguity in the wording of questions or statements can affect the **reliability** of a research instrument as respondents may interpret the questions differently at different times, resulting in different responses.




- 2) **The physical setting** – In the case of an instrument being used in an interview, **any change in the physical setting at the time of the repeat interview may affect the responses given by a respondent, which may affect reliability.**
  
  - 3) **The respondent's mood** – A change in a **respondent's mood** when responding to questions or writing answers in a questionnaire can change and may affect the reliability of that instrument.
- 

4) **The interviewer's mood** – As the mood of a respondent could change from one interview to another so could the **mood, motivation and interaction of the interviewer**, which could affect the responses given by respondents thereby affecting the reliability of the research instrument.

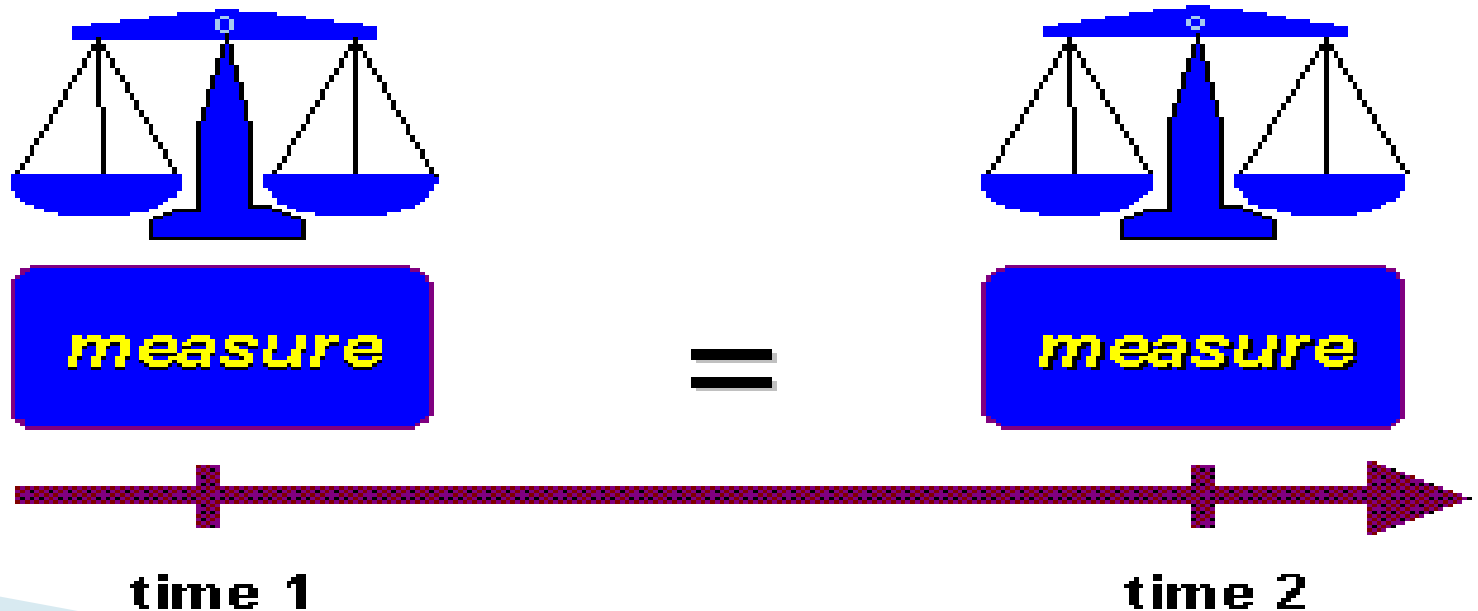


**5) The nature of interaction** – In an interview situation, the interaction between the interviewer and the interviewee can affect responses significantly. During the repeat interview the responses given may be different due to a change in interaction, which could affect reliability.



# Methods of determining the reliability of an instrument

1. Test/retest – Test-Retest Reliability: Used to **assess** the consistency of a measure from one time to another.



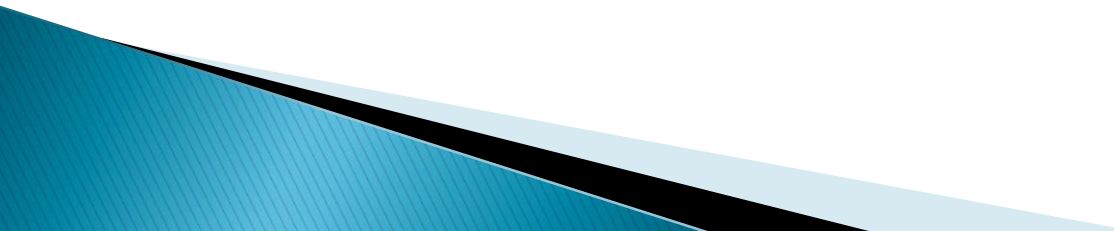
- The greater the value of the ratio, the higher the reliability of the instrument. As an equation,

$$(\text{Test score}) / (\text{retest}) = 1$$

Or

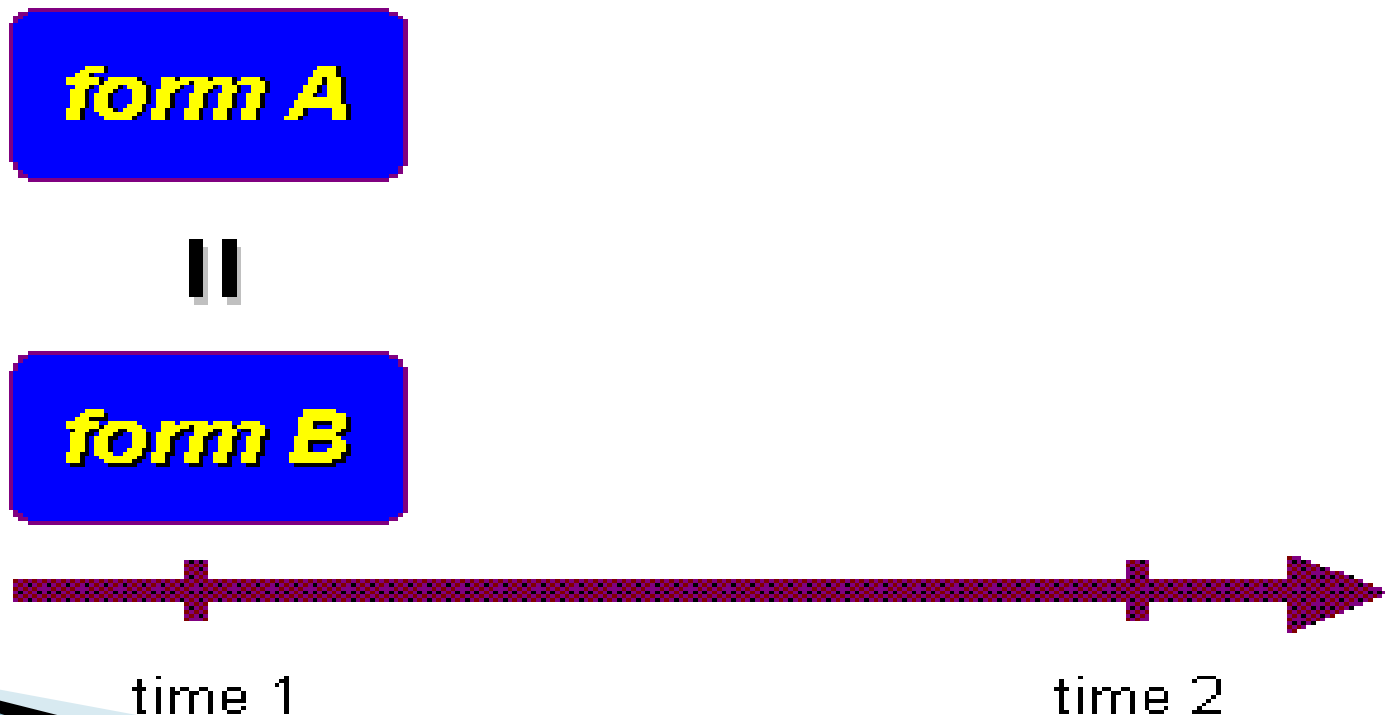
$$(\text{Test score}) - (\text{retest}) = 0$$


- A ratio of **1** shows 100 per cent reliability (no difference between test and retest) and any deviation from it indicates less reliability – the less the value of this ratio, the less the reliability of the instrument.

- Expressed in another way, **zero** difference between the test and retest scores is an indication of 100 per cent reliability.
  - The greater the difference between scores or findings obtained from the two tests, **the** greater the unreliability of the instrument.
- 

## 2. Parallel forms of the same test – Parallel-Forms

Reliability: Used to assess the consistency of the results of **two tests constructed in the same way** from the same content domain.



- In this procedure you **construct two instruments** that are intended to measure the **same phenomenon**.
  - The results obtained from **one test are compared with those obtained from the other**. If they are similar, it is assumed that **the instrument is reliable**.
- 

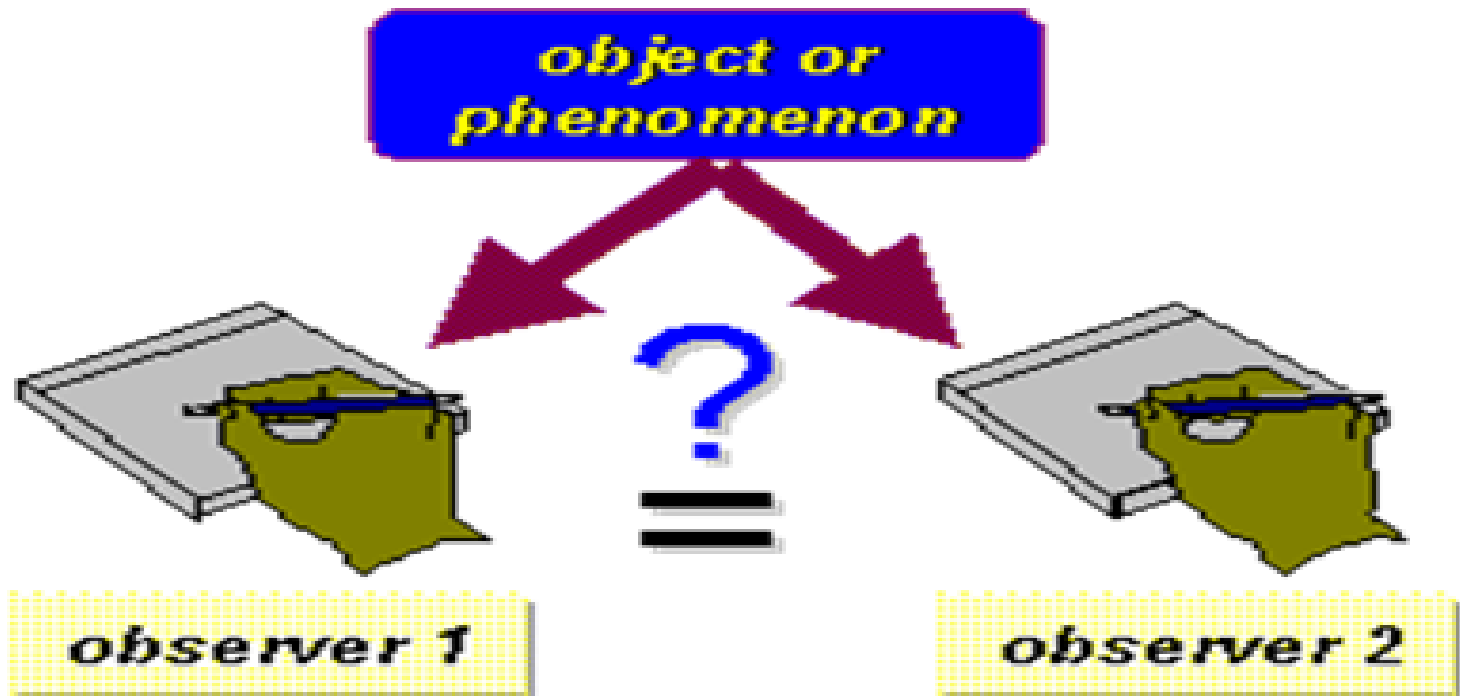


- The main advantage of this procedure is that it does not suffer from the problem of recall found in the test/retest procedure.

- A disadvantage is that you **need to construct two instruments** instead of one. Moreover, it is extremely difficult to construct two instruments that are comparable in their measurement of a phenomenon.

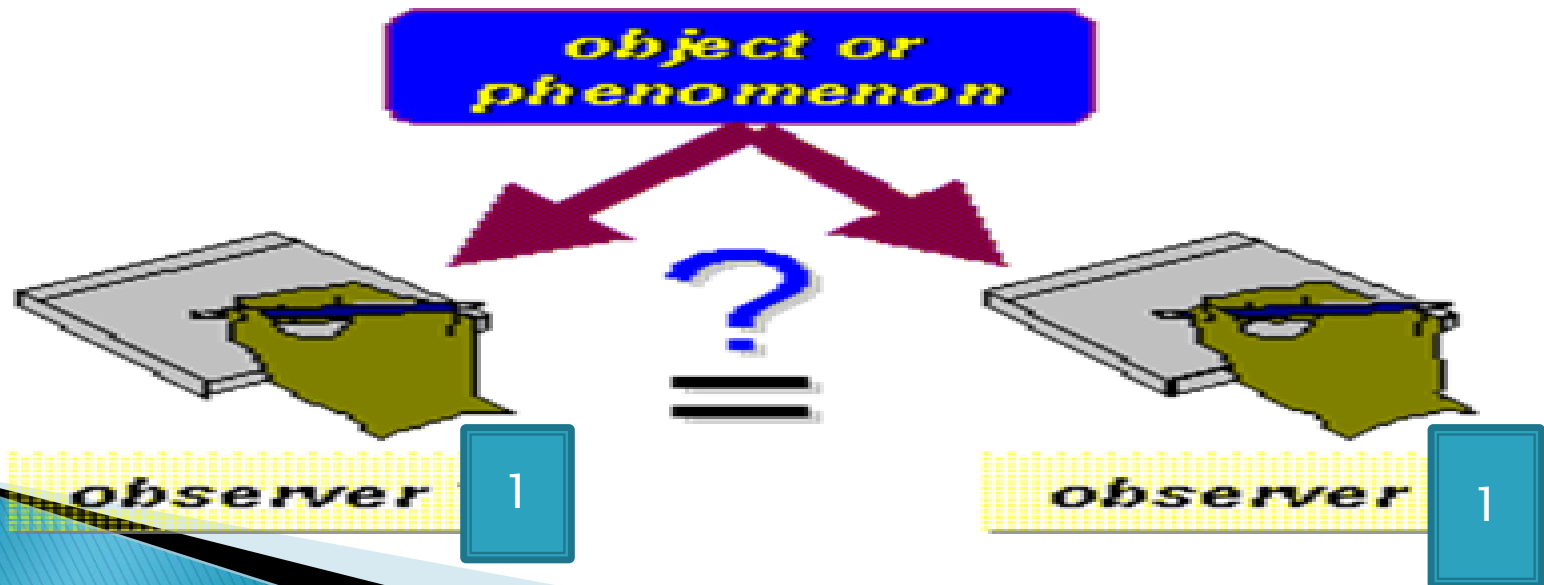
### 3. Inter-Rater or Inter-Observer Reliability:

Inter-Rater Reliability: Used to assess the degree to which different raters/observers give consistent estimates of the same phenomenon.



## 4- Intra-rater reliability

Intra-rater reliability refers to the consistency of the data recorded by one rater over several trials and is best determined when multiple trials are administered over a short period of time.



# An evaluation of the inter-rater and intra-rater reliability

- Intra-rater reliability refers to the consistency of the data recorded by one rater over several trials and is best determined when multiple trials are administered over a short period of time.
- Inter-rater reliability refers to the consistency of data recorded by two or more raters, measuring the same subjects over a single trial.



**THANK  
YOU**

# Research Ethics

**Dr. Mohammed Essam**  
**Lecturer of Physical Therapy**  
**South Valley University**

**What is ethics?**

**What is Research?**

**What exactly is  
research Ethics?**

Ethics as a  
theoretical  
enterprise

```
graph LR; A[Ethics as a theoretical enterprise] --> B[Meta Ethics: "is a branch of analytic philosophy that explores the status, foundations, and scope of moral values, properties, and words"]; A --> C[Normative Ethics: addresses the question of 'What ought to be done?' Normative Ethical theorists seek to provide action guides and codes.]; A --> D[Applied Ethics: domain specific ethics (Business, biomedical; engineering, etc.)].
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**Meta Ethics:** “is a branch of analytic philosophy that explores the status, foundations, and scope of moral values, properties, and words”

**Normative Ethics:** addresses the question of ‘What ought to be done?’ Normative Ethical theorists seek to provide action guides and codes.

**Applied Ethics:** domain specific ethics (Business, biomedical; engineering, etc.).



# Ethics

- ❖ Discipline dealing with what is **proper course** of action for person
- ❖ A branch of philosophy that looks at **what is good** and **what is bad**.
- ❖ A system of obligation that we have **towards others**.
- ❖ Also known as moral philosophy, involves, systematising, defending, and recommending concepts of **right and wrong behaviour**.
- ❖ A study of **principles** guiding the **good of the individual** within the context of **social interactions** and the **community**.

**Univesality and objectivity** - Research should be designed in a manner that allows any competent researcher to conduct a similar study and generate same findings.

**Originality of research**

**work:** original ideas backed with appropriate evidence in a clear, logical and convincing argument that illustrates critical and analytical thinking.



**Generalisability of**

**findings:** extent to which sample used in the research project reflects the broader population of interest.

**Scientific Rigour** (truth is accepted if there is sufficient evidence to support claims made through the research process.

# Research Ethics therefore are:

1. A code of guidelines on how to conduct scientific research in a morally acceptable way.

2. Principles and standards that help researchers to uphold the value and standards of knowledge construction.

**Ethical considerations come into play at six stages of research**

Conceptualization and design of the study (scientific merit, identify risks and ways to mitigate the risks).

When participants are recruited (the process of informed consent, right to privacy).

Protection of confidentiality and anonymity.

During the intervention or measurement procedure to which participants are subjected (management of risk).

In the release of results obtained

After the release of results (ensure that participants and communities involved in the research benefit)

## Another way of looking at research ethics is by looking at unethical research conduct:

- 1) Deception (issues of full disclosure): (Withholding information about the aim of the study, Misleading participants about the risks inherent in participating in the study).
- 2) Plagiarism.
- 3) Conducting research that does not have a scientific base (ill-formed problem statement).

## Another way of looking at research ethics is by looking at unethical research conduct:

- 4) Lack of objectivity and integrity in the design and conduct of research: (not identifying the methodological constraints of the study that determine the validity of the findings, misinterpretation of results, not providing details of theories and methods that might be relevant in the interpretation of research findings).
- 5) Fabrication or falsification of data.
- 6) Not following the appropriate ascription of authorship to a publication.

## Another way of looking at research ethics is by looking at unethical research conduct:

- 7) Not respecting the right to privacy.
- 8) Not respecting the right to anonymity and confidentiality.
- 9) Not respecting rights of vulnerable groups (Children, Mentally handicapped individuals, The aged, Prisoners, Illiterate, Those with low social status).
- 10) Not having due consideration for the environment.

## Fundamentally research ethics are:

- ❖ The way of conducting the research enterprise such that the three fundamental principles of research (respect, beneficence and justice) are upheld.
- ❖ Ethical research must conform to the national and international accords and prescripts.



## Respect

Respect for research participants (informed consent).

Respect for sponsors of research.

Respect for communities where participants come from.

Respect for knowledge and academic community.

### PRINCIPLES OF RESEARCH ETHICS

Risks and benefits should be distributed in an equitable manner when recruiting participants

Benefits must be weighed against potential risk that a person might have by participating

Research should only be justified if its conduct and result will be of benefit to the participants.

How the community will benefit should be clear from the research protocol.

**Justice:** researchers should not place one group of people at risk solely for the benefit another.

**Beneficence:** the researcher is responsible for the mental, physical and social wellbeing of the participant throughout the participation in the study.

# Why be concerned with research ethics?

- 1. Professional Responsibility.**
- 2. To avoid reputational damage.**
- 3. Research can be harmful to:** participants, researchers, institutions, research communities.
- 4. To avoid litigation: by follow** ways in which a researcher can alter or improve its practices to avoid potential conflicts with clients, patients, institutions, sponsors and others.

# Informed Consent

- ❖ A consent given by well informed potential participants about the nature of the research procedure, scientific purpose, and about the risks and benefits of the study, must be addressed by laying out the details out in the language the participant understands, in a culturally acceptable way.
- ❖ Informed consent is given without subjecting the potential participant to coercion, intimidation or undue influence.

# Stages and Process of Informed Consent

## Stages of informed consent

## Informed Consent Activities

Before the commencement of the study

- ❖ Assessment of the local culture.
- ❖ Identification of risks and benefits before and after the study.
- ❖ Pilot testing.

At the beginning of the study

- ❖ Information is presented with the aid of support material to enhance understanding of the research aims and objectives.
- ❖ Risks and benefits of the study are presented.
- ❖ Understanding is assessed.

During the study

- ❖ Reinforce key ethical principles.

# Key Elements of Informed Consent

1. Description of research aims and objectives.
2. Description of potential risks.
3. Description of expected benefits.
4. Explanation of confidentiality and anonymity of participants.
5. Explanation of participants rights including the fact that participation is voluntary.
6. Explanation of issues relating to remuneration/compensation for injuries.

# How To Submit A Proposal For Ethical Clearance

**The proposal submitted for ethical approval should demonstrate that each of the following ethical aspects aren't only addressed, but are discussed in a logical and cogent fashion:**

1. Respect and dignity of participants.
2. Privacy and confidentiality.
3. Balance of benefits and risks.
4. Sampling plan – fair participant selection.
5. Competence and capacity of researcher.
6. Protocols and procedures followed in dealing with minors, vulnerable persons (if applicable).

# Difference between clinical and social science research

	Clinical Research	Social Science Research
<b>Definition</b>	A research study intended to test safety, quality, effectiveness of new and/or existing or old medicines, medical devices and/or treatment options, using human participants.	A systematic recording and analysis of data that may lead to generaliseable, principles and theories resulting in prediction and possibly management of behaviour and events in society.
<b>Research activities</b>	Invasive and non-invasive procedures that may include surgical intervention, removal of body tissues/ fluids, administration of chemical substances, observation, administration of questions etc.	Review of literature, review of data, interviews, focus groups, observations, administration of survey instruments, or tests etc.
<b>Phases or steps followed</b>	Four phases	More or less eight phases (depending on research questions and design of the study)

# Phases of research: clinical vs social

## Clinical Trials

**PHASE I**: A new drug, vaccine or medical device is tested in a small group of healthy persons for the very first time. The aim is to determine the general safety, the correct dosage and negative effects.

**PHASE II**: Clinical trials the new drug, vaccine or medical device in a larger group (several hundred people)

**PHASE III** : testing to several thousand people

**PHASE IV**: clinical trials done to several thousand people after the new drug, vaccine or medical drug has been registered and licensed for sale by the Medical Control Council

## Social Research

**PHASE 1**: problem identification

**PHASE2**: problem definition

**PHASE 3**: development of a theoretical framework

**PHASE 4**: hypothesis formulation or literature review

**PHASE 5**: research design

**PHASE 6**: data collection

**PHASE 7**: data analysis

**PHASE 8**: report writing and dissemination of findings



Thank

You



Becky & Steve



# Critical Appraisal

**Dr. Mohammed Essam**

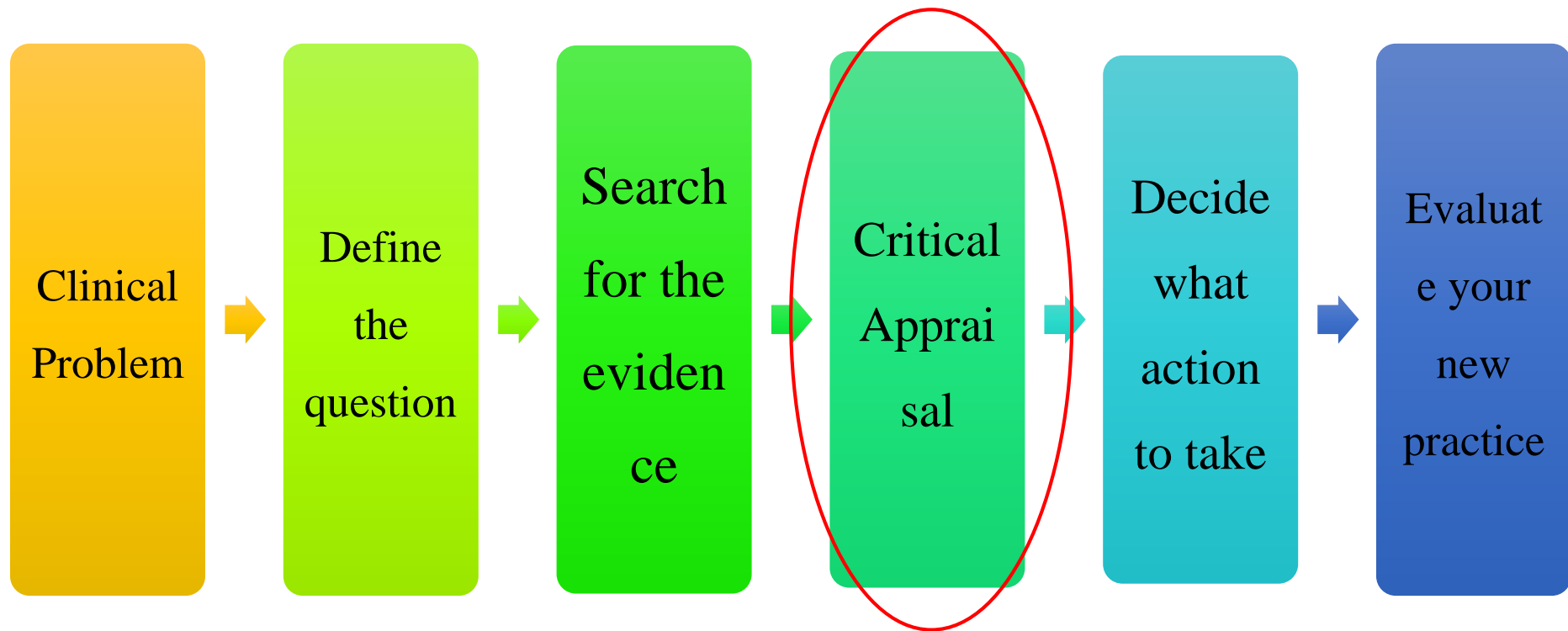
**Lecturer of Physical Therapy**

**South Valley University**

# What is critical appraisal?

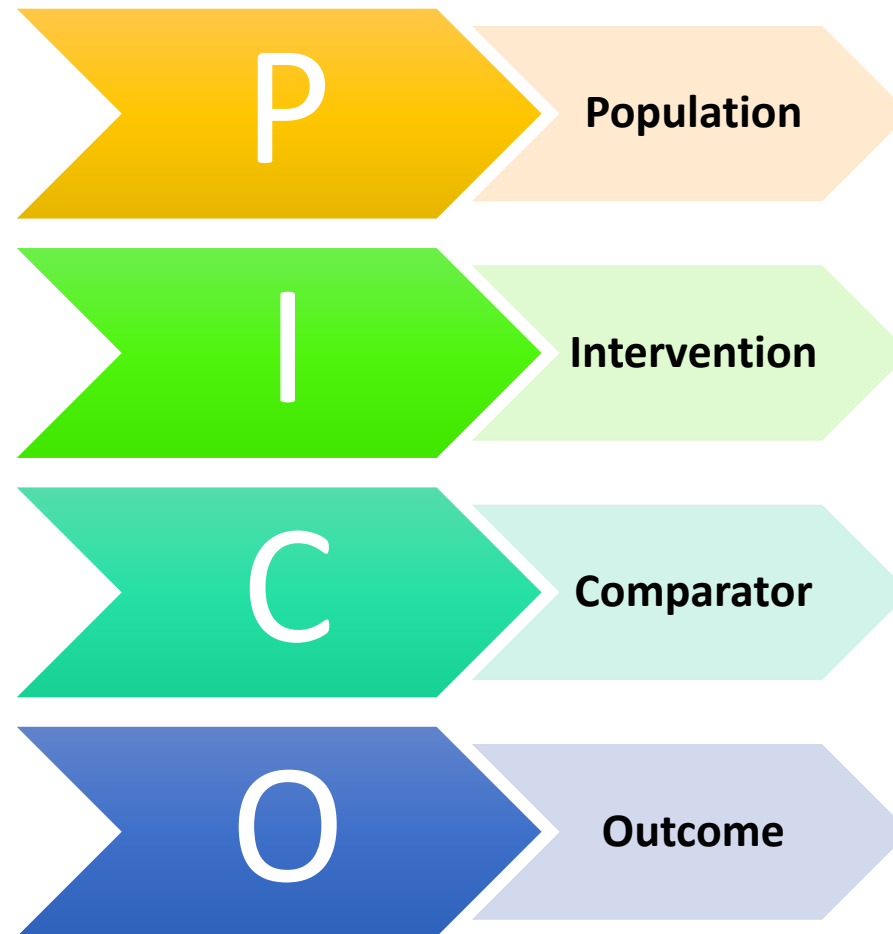
- **Carefully** and **systematically** evaluate research to assess:
  - **Validity** (is these findings trustworthy?)
  - **Value** (what do the results show?)
  - **Relevance** (How do these results relate to my clinical practice?)

**Critical appraisal**: a key component of evidence based medicine.



# How to critically appraise an article

## 1- Asking the right question



	1	2	3	4
	Patient or Problem	Intervention (a cause, prognostic factor, treatment, etc.)	Comparison Intervention (if necessary)	Outcomes
Tips for Building	Starting with your patient, ask “How would I describe a group of patients similar to mine?” Balance precision with brevity.	Ask “Which main intervention am I considering?” Be specific.	Ask “What is the main alternative to compare with the intervention?” Again, be specific.	Ask “What can I hope to accomplish?” or “What could this exposure really affect?” Again, be specific.
Example	“In patients with heart failure from dilated cardiomyopathy who are in sinus rhythm ...”	“... would adding anticoagulation with warfarin to standard heart failure therapy ...”	“... when compared with standard therapy alone ...”	“... lead to lower mortality or morbidity from thromboembolism. Is this enough to be worth the increased risk of bleeding?”

## 2- Choosing right study design

- Some study designs are **not appropriate** to answer certain questions
- All study designs are prone to **different biases**.



# Pyramid of evidence





**So are RCTs the gold standard for  
evidence?**



**.....depends**

# Limitations of RCTs

- 1) Excellent vs Poor RCTs – **quality varies.**
  - Impact on interpretation of result  
(external validity)?
- 2) **Expensive** and **time consuming.**
- 3) May not always be the **right study design**  
to answer that question.

### 3) Validity.

- is these findings trustworthy?
- Methods to **check** that the **biases** for which that **particular study design** is prone have been **minimized**.

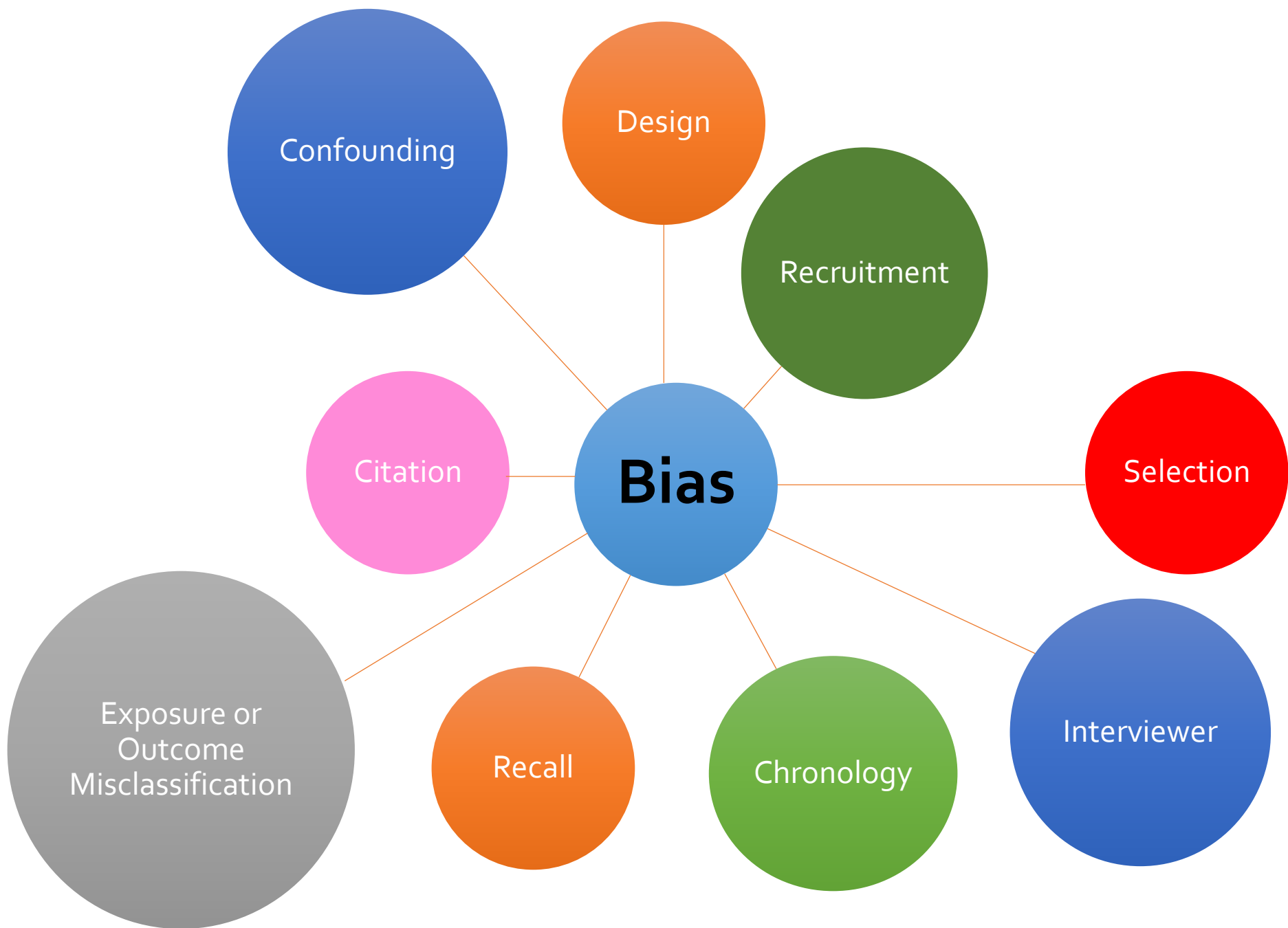
### 3) Results / Value.

### 4) Clinical Relevance.

# Bias:

“The **systematic deviation** of the results of a study from the **truth** because of the way it has been **conducted**, **analyzed** or **reported**”





# Sources of bias in clinical trials

**Table 1. Key sources of bias in clinical trials<sup>2</sup>**

<b>Selection bias</b>	Biased allocation to comparison groups
<b>Performance bias</b>	Unequal provision of care apart from treatment under evaluation
<b>Detection bias</b>	Biased assessment of outcome
<b>Attrition bias</b>	Biased occurrence and handling of deviations from protocol and loss to follow up

# Assessing Trials of effectiveness

## Questions to ask:

1. Are the results of the trial valid?
2. What are the results?
3. Will the results help locally?

# Checklists for clinical trials



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CONSORT stands for Consolidated Standards of Reporting Trials and encompasses various initiatives developed by the CONSORT Group to alleviate the problems arising from inadequate reporting of randomized controlled trials.

#### CONSORT 2010 Key Documents

- [CONSORT 2010 Checklist](#)
- [CONSORT 2010 Flow Diagram](#)
- [CONSORT 2010 Statement](#)
- [CONSORT 2010 Explanation and Elaboration Document](#)

**CEBM** CENTRE FOR EVIDENCE-BASED MEDICINE

The logo for the Centre for Evidence-Based Medicine (CEBM) features a stylized white outline of a city skyline on a dark blue background.

## Critical Appraisal Skills Programme (CASP)

*Making sense of evidence*



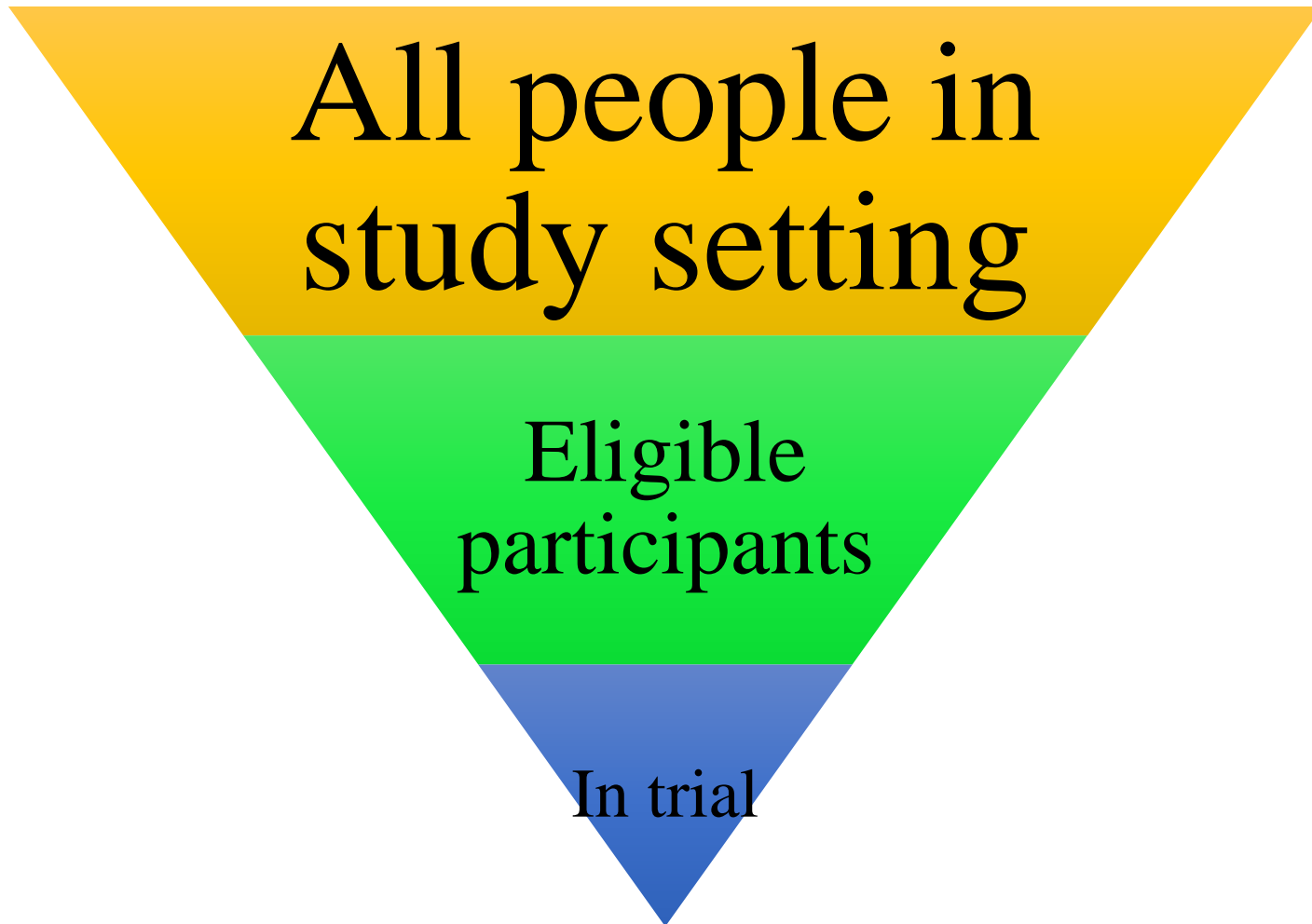
# 11 useful questions for critical appraisal of a randomized trial

1. Did the trial address a clearly focused issue?  Yes  Can't tell  No

Consider: An issue can be 'focused' in terms of

- The population studied
- The intervention given
- The comparator given
- The outcomes considered

**Representative:** Are the trial subjects representative of patients in this setting?



2. Was the assignment of patients to treatments randomised?

Yes

Can't tell

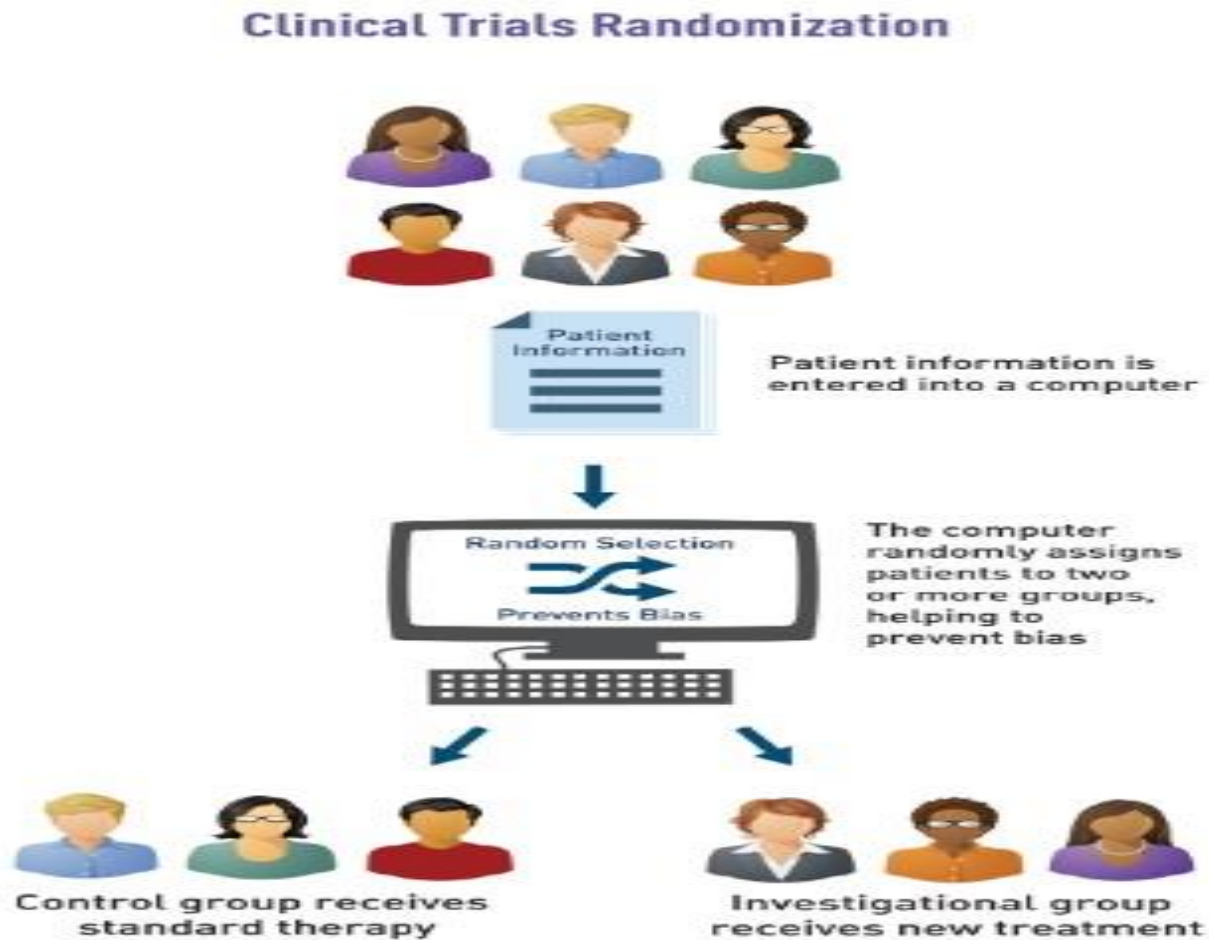
No

Consider:

- How was this carried out, some methods may produce broken allocation concealment
- Was the allocation concealed from researchers?

# Why randomize?

- Minimizes measured and unmeasured confounding.



# Minimizing allocation bias

- Centralized computer randomization the best.
- Other methods such as sealed envelopes doubtful.
- **Non randomized:** date of birth, alternate patients  
alternate days, etc.



**If answer to first two questions is**

**no....**



## Detailed questions

### 3. Were patients, health workers and study personnel blinded?

Consider:

- Health workers could be; clinicians, nurses etc
- Study personnel – especially outcome assessors

Yes

Can't tell

No



4. Were the groups similar at the start of the trial?

Yes

Can't tell

No

Consider: Look at

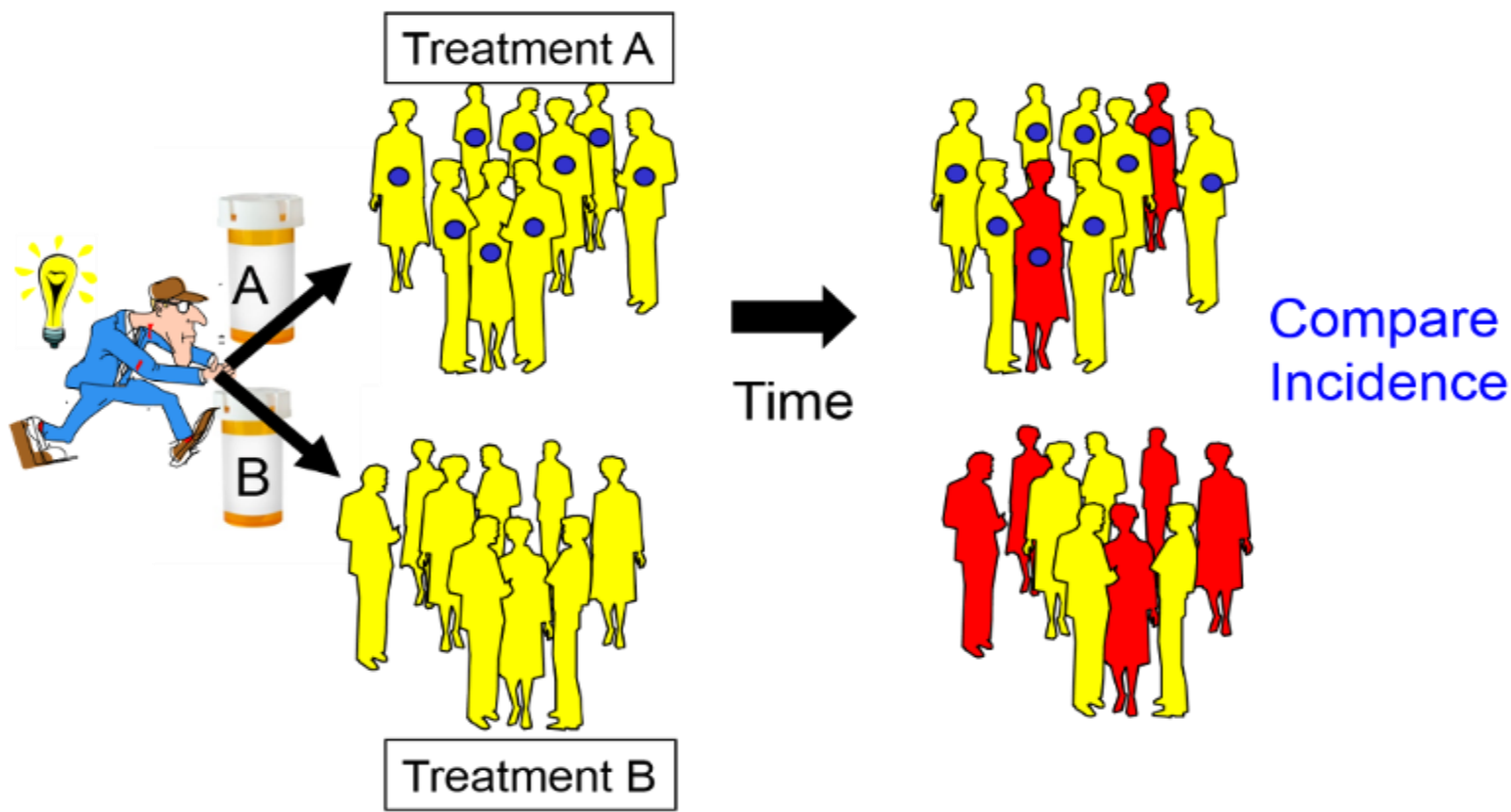
- Other factors that might affect the outcome such as age, sex, social class, these may be called baseline characteristics





5. Aside from the experimental intervention,  
were the groups treated equally?

Yes  Can't tell  No



6. Were all of the patients who entered the trial properly accounted for at its conclusion?

Yes

Can't tell

No

Consider:

- Was the trial stopped early?
- Were patients analysed in the groups to which they were randomised?



## (B) What are the results?

### 7. How large was the treatment effect?

Consider:

- What outcomes were measured?
- Is the primary outcome clearly specified?
- What results were found for each outcome?
- Is there evidence of selective reporting of outcomes?

### 8. How precise was the estimate of the treatment effect?

Consider:

- What are the confidence limits?
- Were they statistically significant?

## (C) Will the results help locally?

9. Can the results be applied in your context?

(or to the local population?)

Consider:

- Do you have reason to believe that your population of interest is different to that in the trial
- If so, in what way?

Yes

Can't tell

No



**10. Were all clinically important outcomes considered?**

Yes  Can't tell  No

Consider:

- Is there other information you would like to have seen?
- Was the need for this trial clearly described?

---

**11. Are the benefits worth the harms and costs?**

Yes  Can't tell  No

Consider:

- Even if this is not addressed by the trial, what do you think?

# Conclusion

- Critical appraisal helps us decide whether evidence is valid, what the results tell us and whether the study is relevant to our setting
- Checklists are available to help
- Don't believe everything you read in journals!