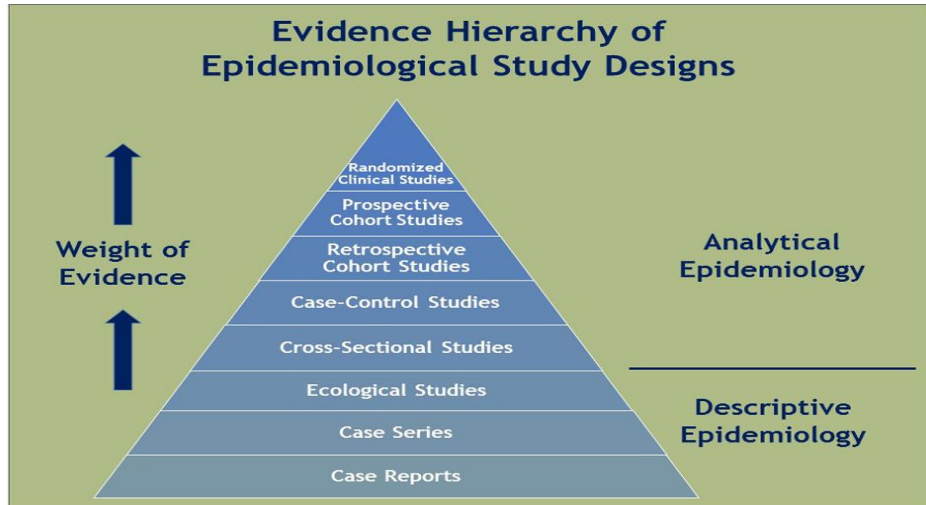


Unit III: Epidemiological Methods/Study Designs... 16 hours



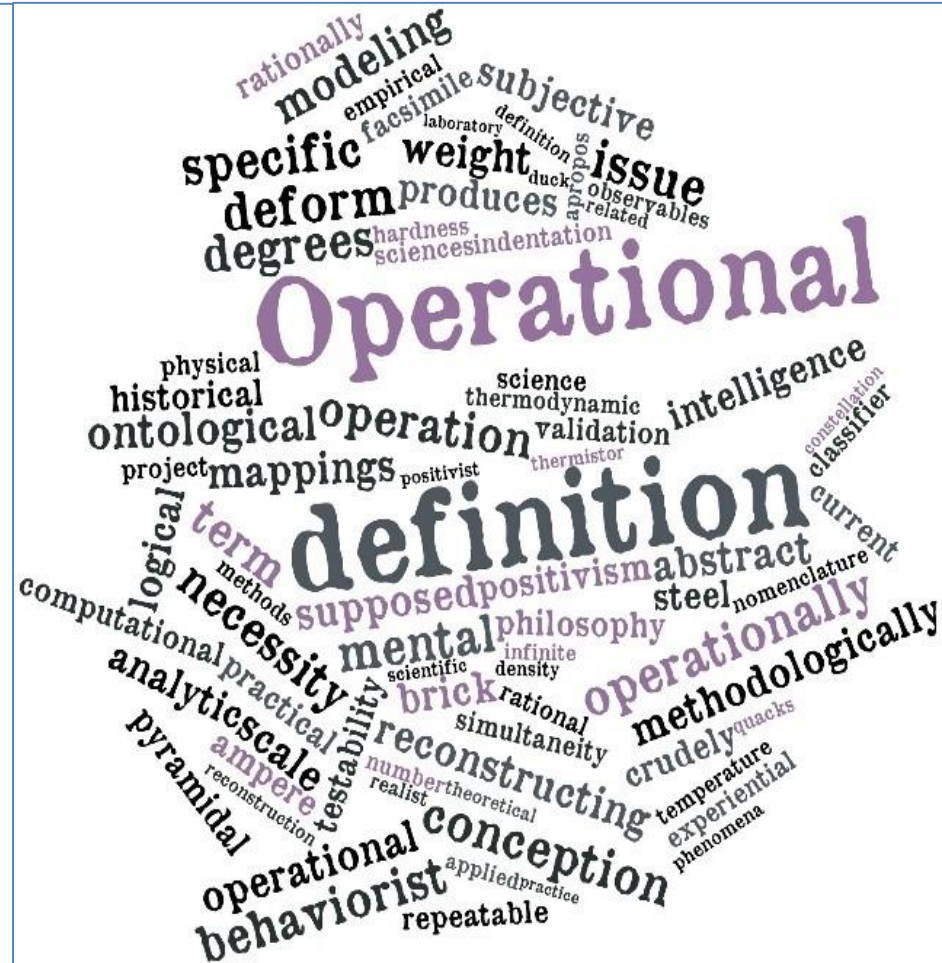
Contents

- **Definition of terms:** Operational definition, contingency table, intervention, randomization, experimental study, interview, observation, questionnaire
- **Epidemiological studies: Observational and Experimental studies;**
- Observational studies: concepts and classifications Descriptive study: case studies and case series
- Analytical studies: Cross-sectional study, ecological study, case-control and cohort study
- Experimental studies: concepts, classifications and principles
- Pre-experimental, quasi experimental, true experimental studies
- Strengths and limitations of observational and experimental studies

Definition of terms

1. Operational definition

- An operational definition is how we (the investigator) decide to measure our the variables in our study (variable = anything that can be measured).
- An operational definition is the statement of procedures the investigator is going to use in order to measure a specific variable.



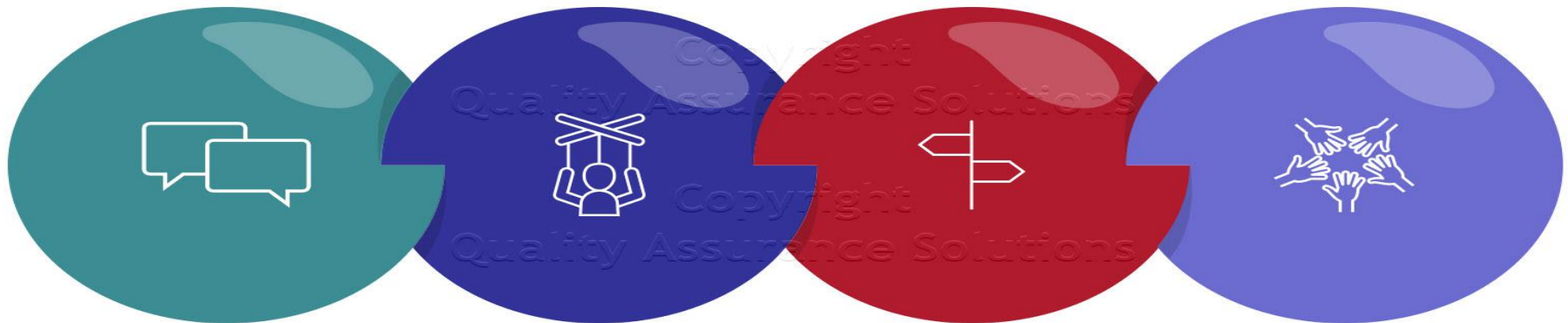
Contd...

- An operational definition is a description of a concept in measurable terms. It is used to remove ambiguity, to serve as a guide for the selection of measurement tools, and to reduce the likelihood of disparate results between different data collection.
- An operational definition, when applied to data collection, is a clear, concise detailed definition of a measure. The need for operational definitions is fundamental when collecting all types of data.

Operational Definitions

- Who creates the operational definition?
 - Developed by the researcher conducting the study
- Why do we have operational definitions
 - Needed for replication of studies
 - Assist in developing inter-rater reliability (all people grade the variable the same way)

Operational Definition



Describes

It describes a precise meaning to the spoken or written word, forming a "common language" between two or more people.

Application

It defines how a word or phrase is used when it is applied in a specific context.

Workable Meaning

Words such as "good," "reliable," "defect," and "uniform" have many meanings unless they are defined in specific terms.

Effective Communication

Avoid misinterpretations, members of your team, both internal and external, customers and suppliers must use the same OD for the same concepts.

Table 5.1 Dictionary and Operational Definitions of Several Terms Commonly Used by Psychologists

For each concept, other operational definitions are possible.

TERM	DICTIONARY DEFINITION	OPERATIONAL DEFINITION
Punishment	Harsh or injurious treatment for an offense	Presentation of 3 milliamp shock for .5 second following certain (specified) behavior
Learning	Acquiring knowledge or skill	Change in behavior (specify kind of behavior) as a function of practice
Anxiety	State of being uneasy, apprehensive, or worried	Sweat gland activity (amount), heart rate (amount), physiological changes (specify), self-reported anxiety on a scale of 1 to 7
Intelligence	Ability to learn or understand from experience	Score on the Stanford–Binet Intelligence Test, score on the Wechsler Intelligence Scale for Children
Thirst	Distressful feeling caused by a desire or need for water	Eighteen hours (or other value) without access to water
Sleep	Recurring condition of rest, no conscious thought, eyes closed, etc.	Specific brain wave frequencies (EEG) for different sleep stages
Guilt	A painful feeling of self-reproach	Score on a personality inventory, self-reported guilt on a scale of 1 to 10

2. Contingency Table

- A contingency table, sometimes called a two-way frequency table, is a tabular mechanism with at least two rows and two columns used in statistics to present categorical data in terms of frequency counts.
- A two-variable table with data categorized jointly by those two variables is known as a contingency table.
- A contingency table (also known as a cross tabulation or crosstab) is a type of table in a matrix format that displays the (multivariate) frequency distribution of the variables.

Contingency Table.....

- A tabular cross classification of data such that subcategories of one characteristics are indicated horizontally (Rows) and other sub categories indicated vertically (columns)

Exposure status	Conditions	
++	A	b
--	c	d

3. Intervention

- Any intentional action designed to result in an outcome.
- Interventions are actions that public health nurses take on behalf of individuals/families, communities, and systems, to improve or protect health status.
- The term 'intervention' is means “any activity undertaken with the objective of improving human health by preventing disease, by curing or reducing the severity or duration of an existing disease, or by restoring function lost through disease or injury”

Examples

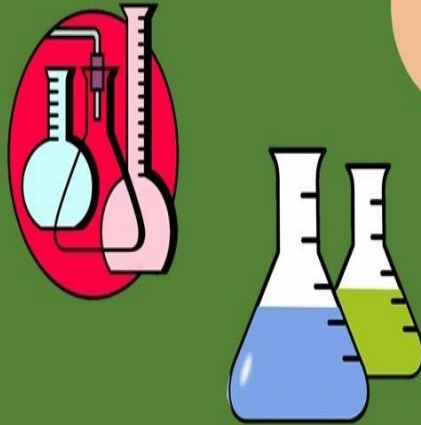
- Screening programs
- Vaccination
- Food and water supplementation
- Health promotion.
- A treatment, procedure, or other action taken to prevent or treat disease, or improve health in other ways



4. Experimental study

- Experimental studies are ones where researchers introduce an intervention and study the effects.
- Experimental studies are usually randomized, meaning the subjects are grouped by chance

Experimental
Design



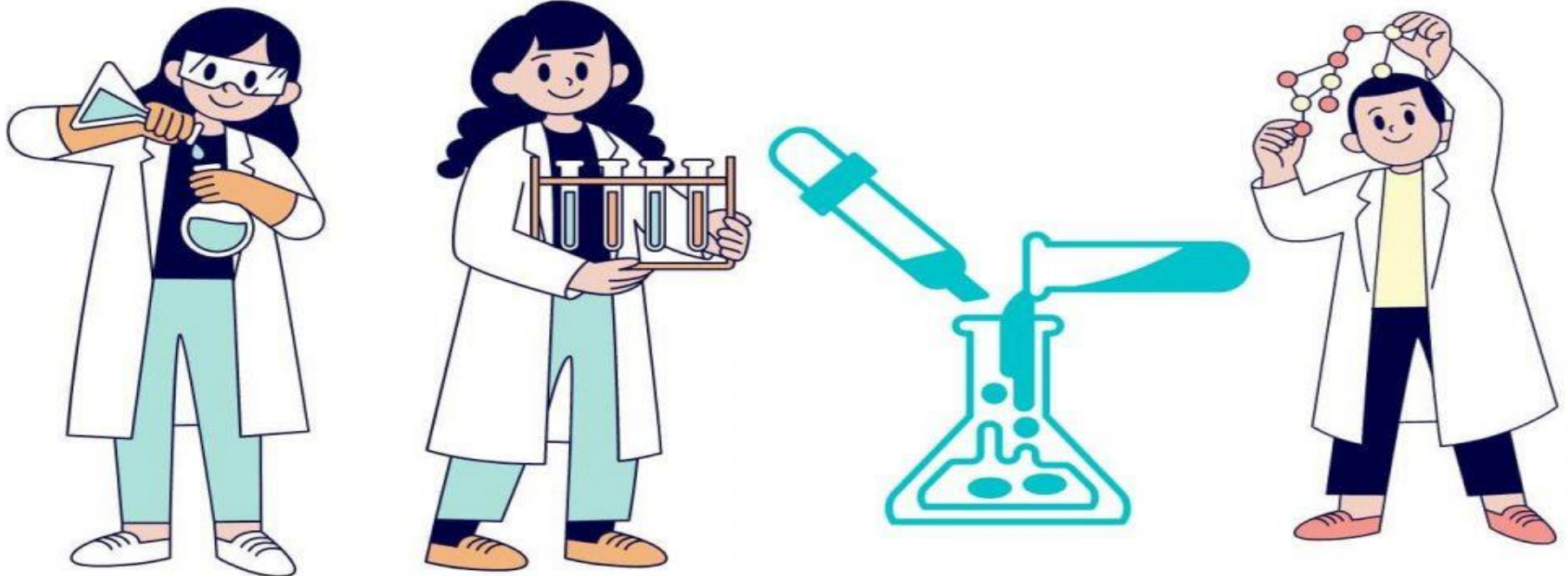
VS

Non-Experimental
Design



The goal of the experimental method is to provide more definitive conclusions about the causal relationships among the variables in a research hypothesis than what is available from correlational research. Experiments are designed to test hypotheses, or specific statements about the relationship between variables.

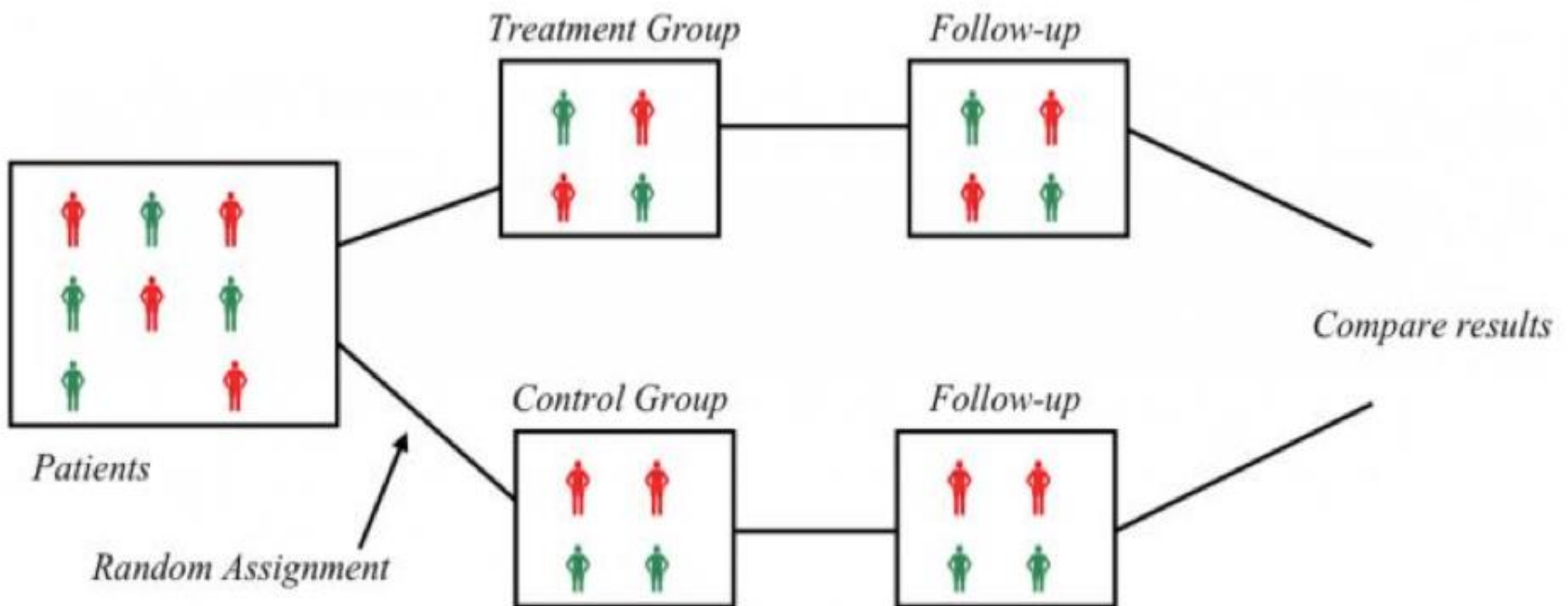
Experimental Research Design



5. Randomization

Randomization is the process of making something random; in various contexts.

It is the method based on chance alone by which study participants are assigned to a treatment group. Randomization minimizes the differences among groups by equally distributing people with particular characteristics among all the trial arms.



6. Interview

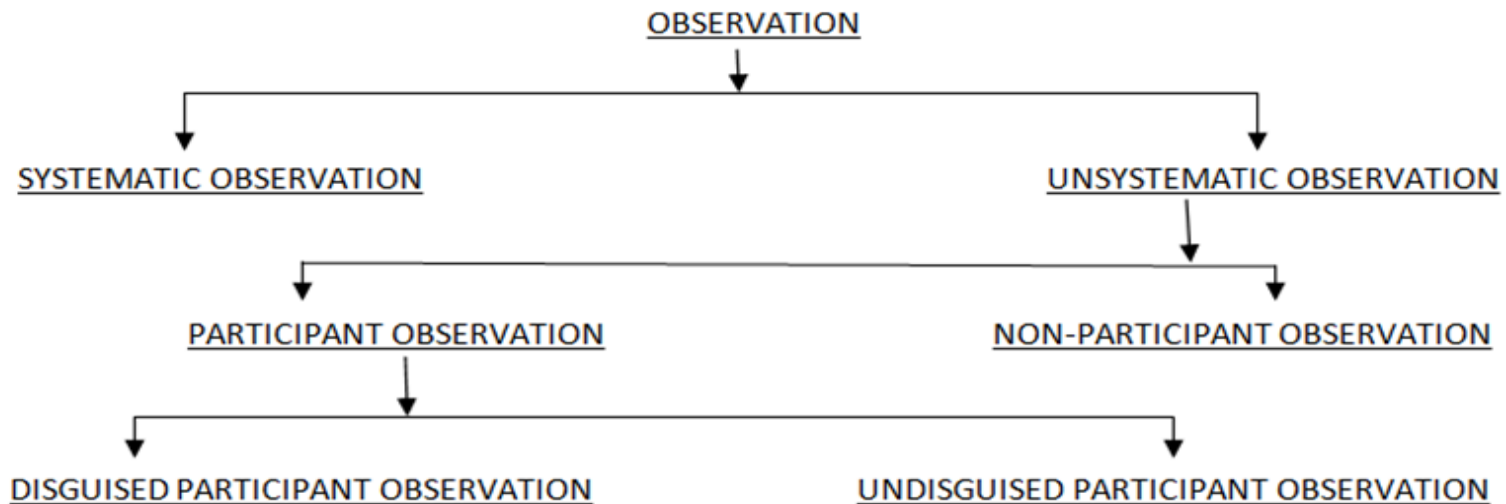
- It is a technique of data generation in which the interviewer asks the relevant questions/ concerns to the interviewee.
- There exists two way information flow between two personnel involved. It may be direct face to face interview or it may be telephonic/ media communication.
- Interview guideline: defined guideline used to facilitate the process of interview. For example Focus group discussion guideline

7. Observation

- The purposeful watch over the event with great attention and authority.



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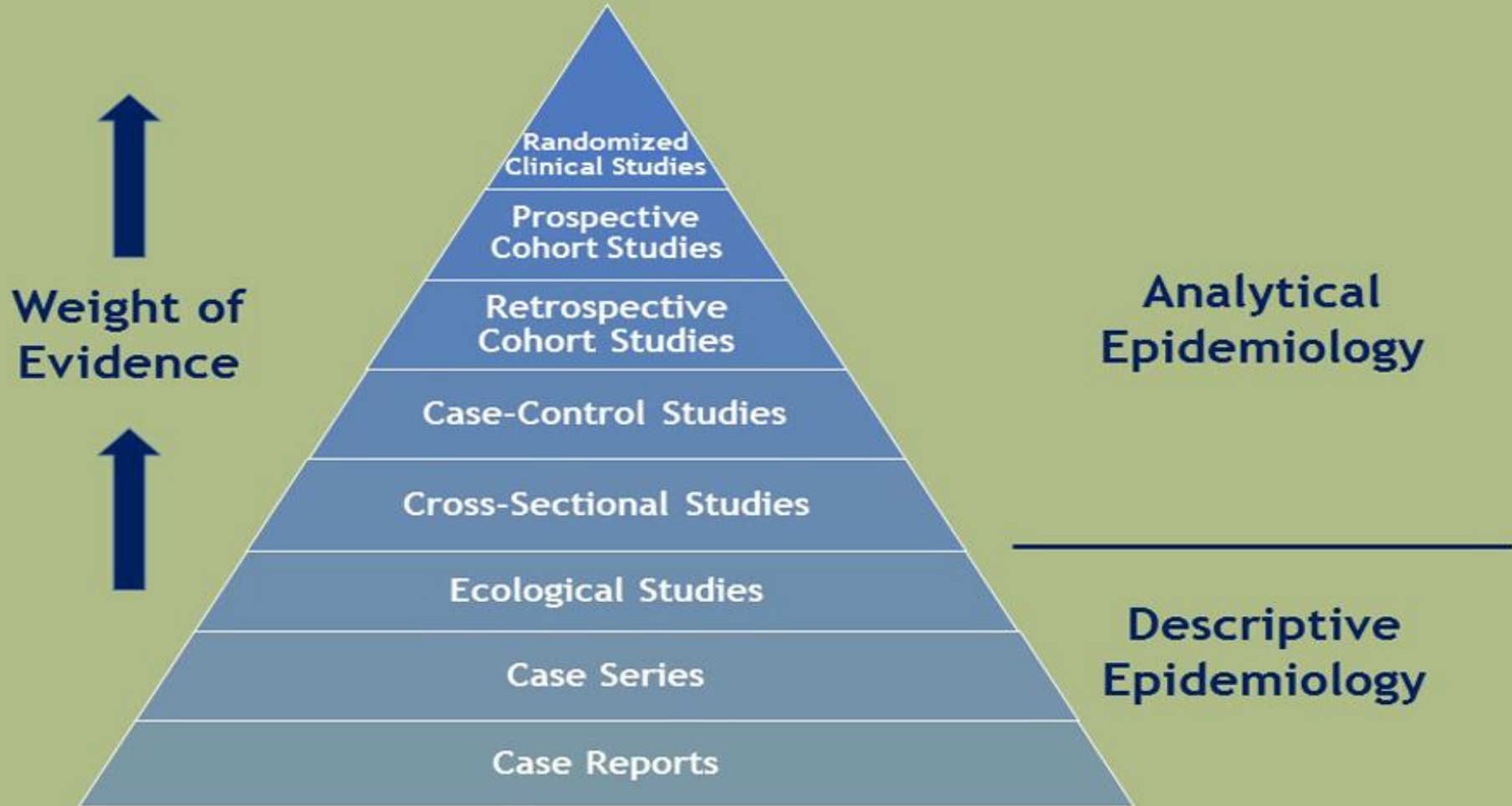


8. Questionnaire

- A set of question designed to gather information specific to the events. It is prepared to lead the information logical manner.
- Mailed questionnaire : readymade set of questionnaire containing preformed questions based on the need of the study concerned.

EPIDEMIOLOGICAL METHODS

Evidence Hierarchy of Epidemiological Study Designs



1. Classification of epidemiological studies on the basis of philosophy adopted

- Epidemiological studies are classified into
 - Conceptual
 - Empirical type.
- Conceptual studies are related to some abstract ideas or
- An empirical study is data based, It can also be called as experimental study.

2. Classification of epidemiological studies on the basis of action over natural course

- **Observational**
- **Experimental**

Observational studies have further subdivisions:

- **Descriptive**
- **Analytical.**

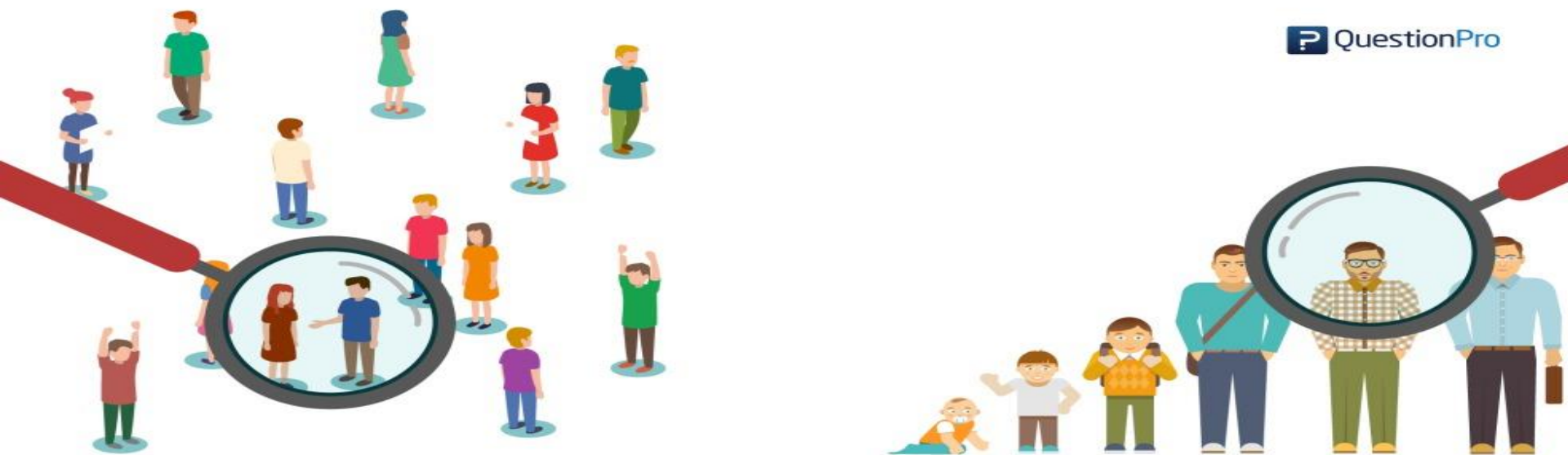
Experimental studies are also subdivided into

- **Clinical trial,**
- **Community trial**
- **Field trial.**

3. Classification of epidemiological studies on the basis time of study

- cross- sectional
- longitudinal.

*Cross- sectional studies are done at **one point in time** while longitudinal studies are performed over a **prolonged period of time** by follow up examinations.*



Cross-sectional study

VS

Longitudinal study

4. Classification on of epidemiological studies on the basis of intervention on natural course

- Non intervention study
- Intervention study

Interventional vs. Non-Interventional Studies

Interventional

*Participants are assigned to receive one or more interventions (or no intervention)
*Evaluate effects of interventions on biomedical or health-related outcomes

Examples:
Diagnostic studies
Screening studies
Treatment studies

Non-Interventional

*Prospective or retrospective studies collecting data and not interfering with the choice of treatment, sample collection, procedures and the treatment itself.

Examples:
Observational studies
Epidemiology studies

EPIDEMIOLOGICAL METHODS / STUDIES

A Practical classification

Epidemiological studies are concerned with the **natural history and etiology of the diseases.**

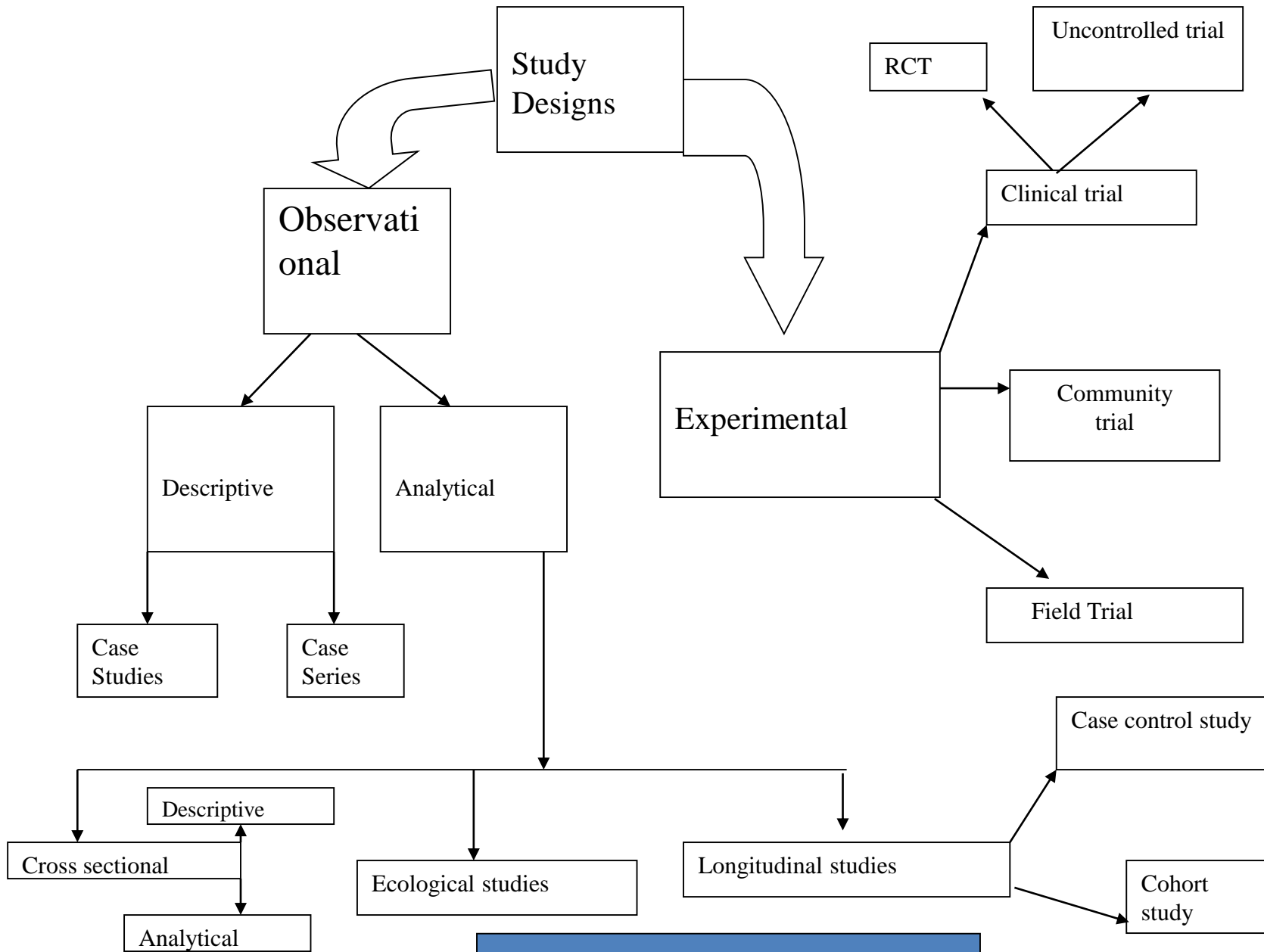


Fig: Study designs

CLASSIFICATION

1. Observational study

2. Experimental/ Intervention study

CLASSIFICATION

Observational study

- Observational study is one in which the nature takes it's own course.
- The investigator only measures the effects but does not intervene anywhere in the whole process.

- *Experimental / Intervention study*

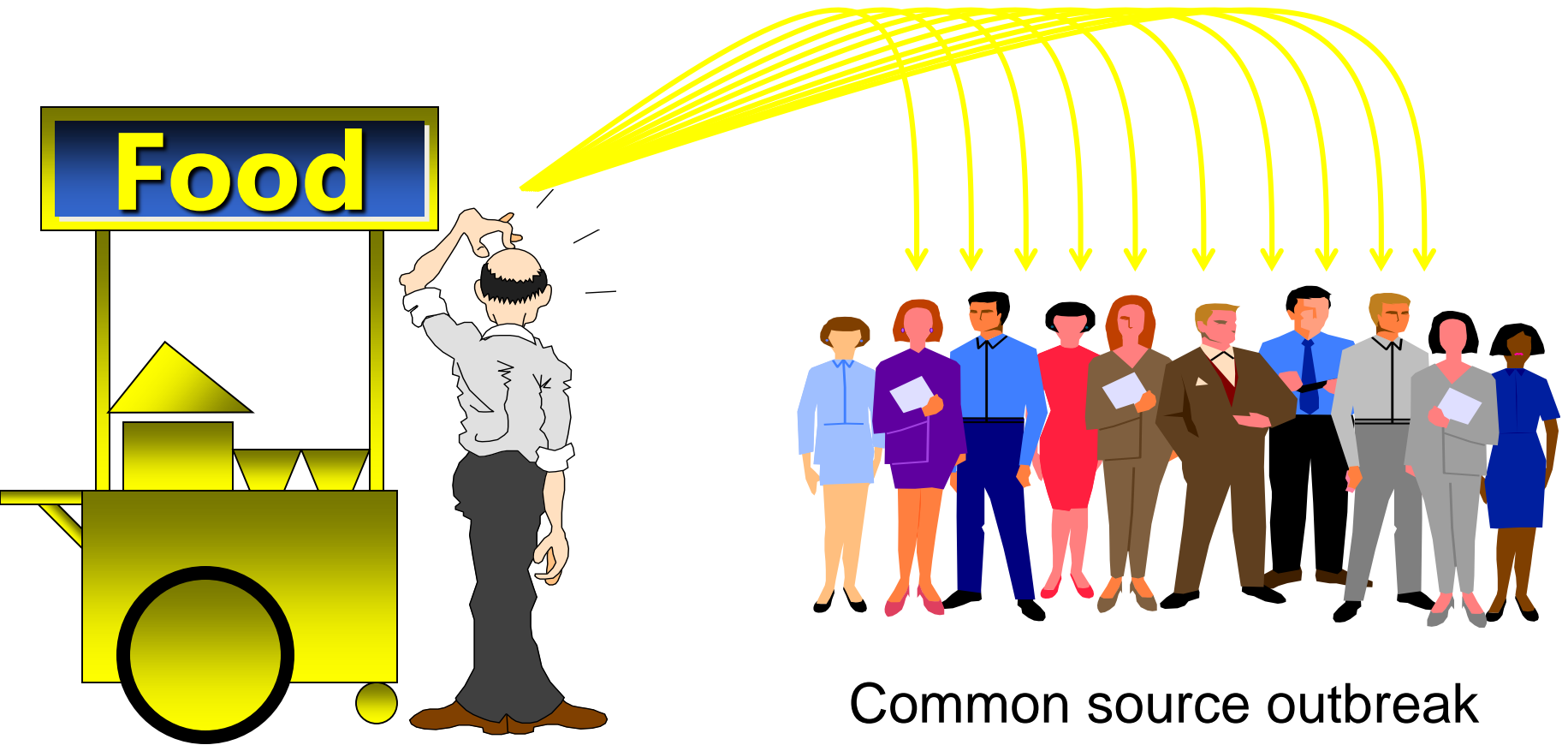
Experimental study is one in which the change is observed after an intervention.

OBSERVATIONAL STUDY

- *Descriptive study*
- *Analytical study*

Descriptive study

Descriptive study is limited only to a description of the occurrence of a disease or an event in a population. Eg. Case report and case series



Analytical study

Analytical study is one in which analysis is done between two variables.

Analytical studies

- Cross sectional
- Ecological
- Longitudinal

Analytical study

- *Cross sectional:*
 - It is based on a single observation on a cross section of population at one point of time.
 - It is useful in case of chronic diseases. It is also called 'Prevalence study'.



Contd...

- **Ecological**: It is based on the study of events in relation to particular attribute in different or same group.
- **Longitudinal**:
It is based on the repeated observation in the same population over a prolonged period of time by means of follow up examinations.



Ecological studies

- Examines **exposures** and **health outcomes**

Average exposure
is related to
Average health outcome
in a population

- **Can also categorise by** age, sex, ethnicity, socio-economic status

Longitudinal study

- ***Case - control Study***
- ***Cohort Study***

Longitudinal study

- ***Case control Study***

It is based on the comparison between the cases and control.

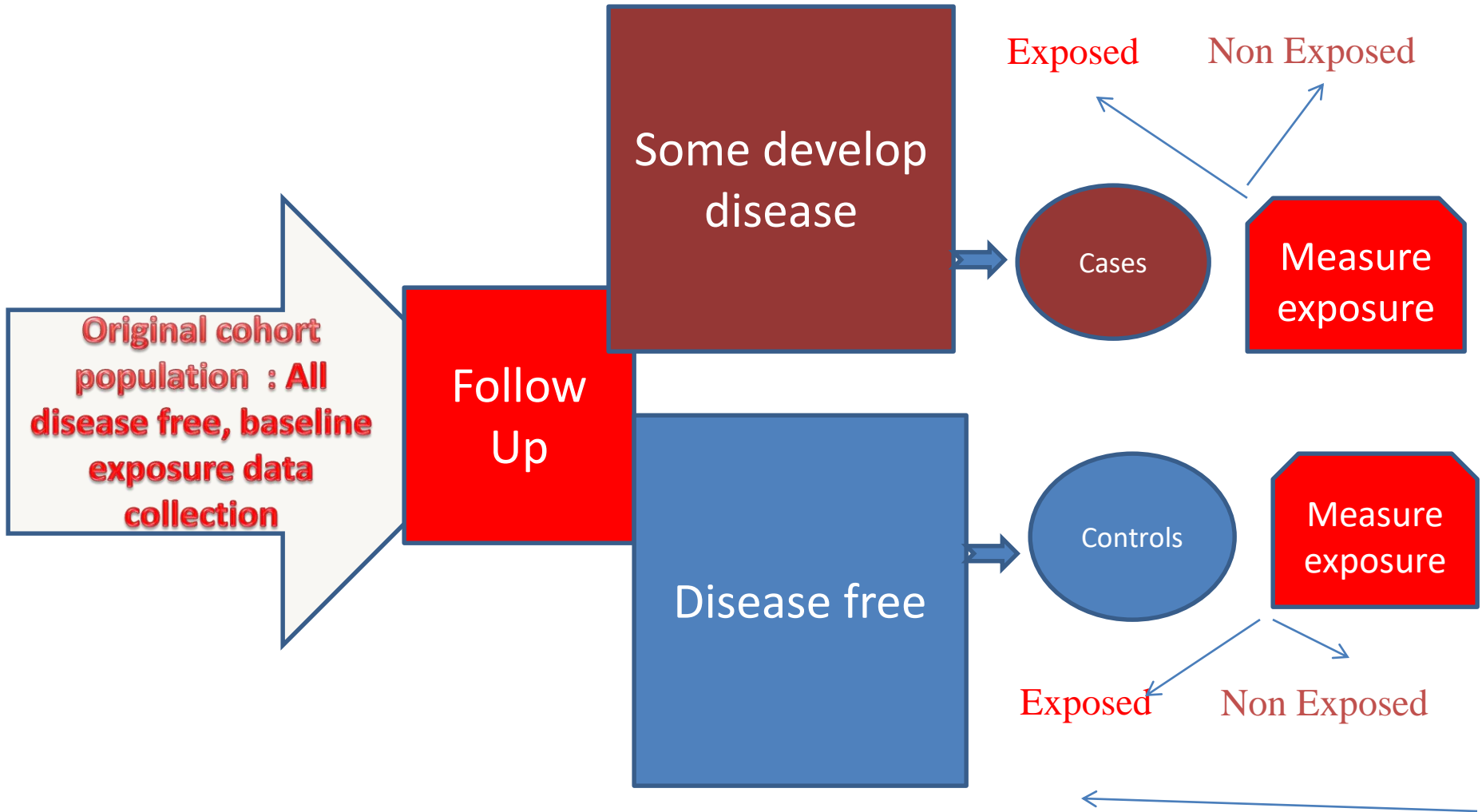
- ***Cohort Study***

Effects are observed among the cohort for a period of time.

What is 'Cohort' ?

Cohort is a group of people who share a common characteristic, e.g., Birth cohort, Marriage cohort, Exposure cohort, etc.

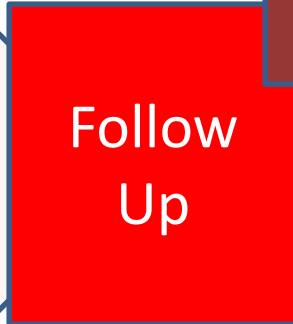
Time



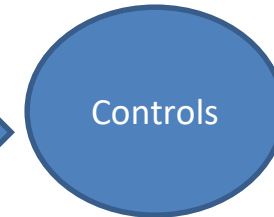
Exposed

Non Exposed

Some develop disease



Original cohort population : All disease free, baseline exposure data collection



Exposed

Non Exposed

Direction of inquiry

Direction of inquiry

Fig: diagram of cohort and Nested case control study

Experimental studies

- Experimental studies are ones where researchers introduce an intervention and study the effects.



Types of
experimental
research
design

Pre-experimental
research design

True experimental
research design

Quasi-experimental
research design

Pre-experimental, quasi experimental, true experimental studies

- **Pre-Experimental Designs**

- Pre-experiments are the simplest form of research design.
- In a pre-experiment either a single group or multiple groups are observed subsequent to some agent or treatment presumed to cause change.
- **Types of Pre-Experimental Design**
 - One-shot case study design
 - One-group pretest-posttest design
 - Static-group comparison

- **Quasi experimental designs**

- A quasi-experimental design aims to establish a cause-and-effect relationship between an exposures and outcomes. However, it does not rely on random assignment of study groups. It is useful tool in situations where true experiments cannot be used for ethical or practical reasons.

True experimental design

True experimental design is a statistical approach to establishing a cause-and-effect relationship between different variables. This is one of the most accurate forms of research designs which provides substantial backing to support the existence of relationships.

Experimental studies

- 1. Randomized Controlled Trial(RCT)/Clinical trial***
- 2. Field trial***
- 3. Community trial***

Contd...

1. Randomized Controlled Trial

It is done among two different randomly selected groups of study elements. It is usually done in hospitals.

2. Field trial

It is done in randomly selected groups of people in the community.

3. Community Trial

Community trials are an extension of field trials. In community trials the study group is the entire community, rather than individuals. Conceptually, the difference is whether or not the intervention is implemented separately for each individual.

SUMMARY

Classification of Epidemiological studies

- *Observational study*
 - a. **Descriptive study**
 - b. **Analytical study**
 - (i) Cross sectional study/Prevalence study
 - (ii) Ecological study
 - (iii) Longitudinal Study
 - (1) Case control study/Backward looking study/Retrospective study
 - (2) Cohort study/Forward looking study/Prospective study/Incidence study
- *Experimental study*
 - a. **Randomized Control Trial**
 - b. **Field Trial**
 - c. **Community Trial**

Epidemiological studies: Observational and Experimental studies

- Observational studies: concepts and classifications
- Descriptive study: case studies and case series
- Analytical studies: Cross-sectional study, ecological study, case-control and cohort study
- Experimental studies: concepts, classifications and principles

Strengths and limitations of observational and experimental studies

Observational Studies

Advantages	Disadvantages
The observation method is an easy method since it usually does not require technical skills.	In the observation method, not everything is observed. Feelings, emotions, and opinions remain unobserved.
The observation method provides high accuracy since the observer directly interacts with the observed.	Observation is a costly method since it requires a lot of things.
It is a universal and standard method that is used all over the world. The observation method describes the phenomenon exactly as it occurs in the natural research environment.	Observation is a very time-consuming process, and there are chances that the observer and the observed will lose interest in it after a certain point in time.
In the observation method, the very minimum cooperation of the respondent is required.	There is absolutely no way of knowing the past life. The researcher has to rely on documents that are not always accurate.

Experimental Design

Strengths

- Controls the influence of confounding variables, providing more conclusive answers
- Randomization eliminates bias due to pre-randomization confounding variables
- Blinding the interventions eliminates bias due to unintended interventions

Weaknesses

- Costly in time and money
- Many research questions are not suitable for experimental designs
- Usually reserved for more mature research questions that have already been examined by descriptive studies
- Experiments tend to restrict the scope and narrow the study question

Thank You!