RESEARCH METHODS

STUDY DESIGNS

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LEARNING OBJECTIVES

1. To identify the definition and functions of RD.
2. To describe how to select our RD.
3. To have a knowledge about the types of RD.
4. To clarify the various components of the methods section in a research.

A STUDY DESIGN (SD)

- Is the Logical model that guides the investigator on how to operate the research problem in a systematic manner.
- So it provides insight how to conduct a research using a particular research methodology.

- ***most problems in studies are due to poor design (to less extend poor analysis)***

- ***results from a single study are seldom definitive (or even clear)***

FUNCTIONS OF RD

1. The RD provides a blueprint for the collection of evidences systematically……
2. It permits the accurate assessment and interpretation of inferences …
3. RD helps to resolve many shortcomings before the study start, and decide alternative ways to solve the RP.

WE SELECT THE STUDY DESIGN ACCORDING TO:

- **Nature of the research question**
- **Objective(s) of the study**
- **Our resources**
- **Our knowledge about types of study design.**

The main types are divided as:

Epidemiological studies:

A. Observational:

I. Descriptive studies:	II. Analytic studies:
1. Case report & case series	1. Case Control study
2. Ecological	2. Cohort study
Cross sectional	

B. Interventional :

. Randomized Clinical Trial (RCT)

. Community trials

. Field trial.

- **Quasi experimental studies.**

OBSERVATIONAL DESCRIPTIVE STUDIES

- Studies that describe the phenomena by person place and time.

- Provide the first important clues about possible determinants of a disease (hypotheses formulation studies)

OBSERVATIONAL DESCRIPTIVE STUDIES

TYPES

- Case Report
- Case Series
- Ecological studies
- **Cross-sectional**
- Biometric study
- Registry based Study
- Systematic review
- **Meta-analysis**

CASE REPORT

- Describes unusual clinical observations, interesting or novel variation of a health related problem.

Advantages:

- simple, quick &easy.
- One of the first steps in outbreak investigation
- Calls attention to a novel observation or hypothesis.

Disadvantages: cannot be generalized (single case represent itself).

CASE SERIES:

Refers to a group of similar cases, to recognize well a clinical pattern and characteristics of specific disease.

Advantages:

- simple, quick &easy.
- One of the first steps in outbreak investigation
- Better recognition of any disease, case definition of new one. (hypothesis)

Disadvantages:

- non-generalizable inferences (small sample size).
- Estimation of risk cannot be done (no comparison).

e.g. recognition of AIDs began with case reports and case series':

- ***pneumocystis carinii* pneumonia (pcp).**
- **kaposi's sarcoma among white young americans.**
- **all of the patients were …….**
- **the case series' led to an initial AIDs case definition for the purposes of identifying additional cases.**

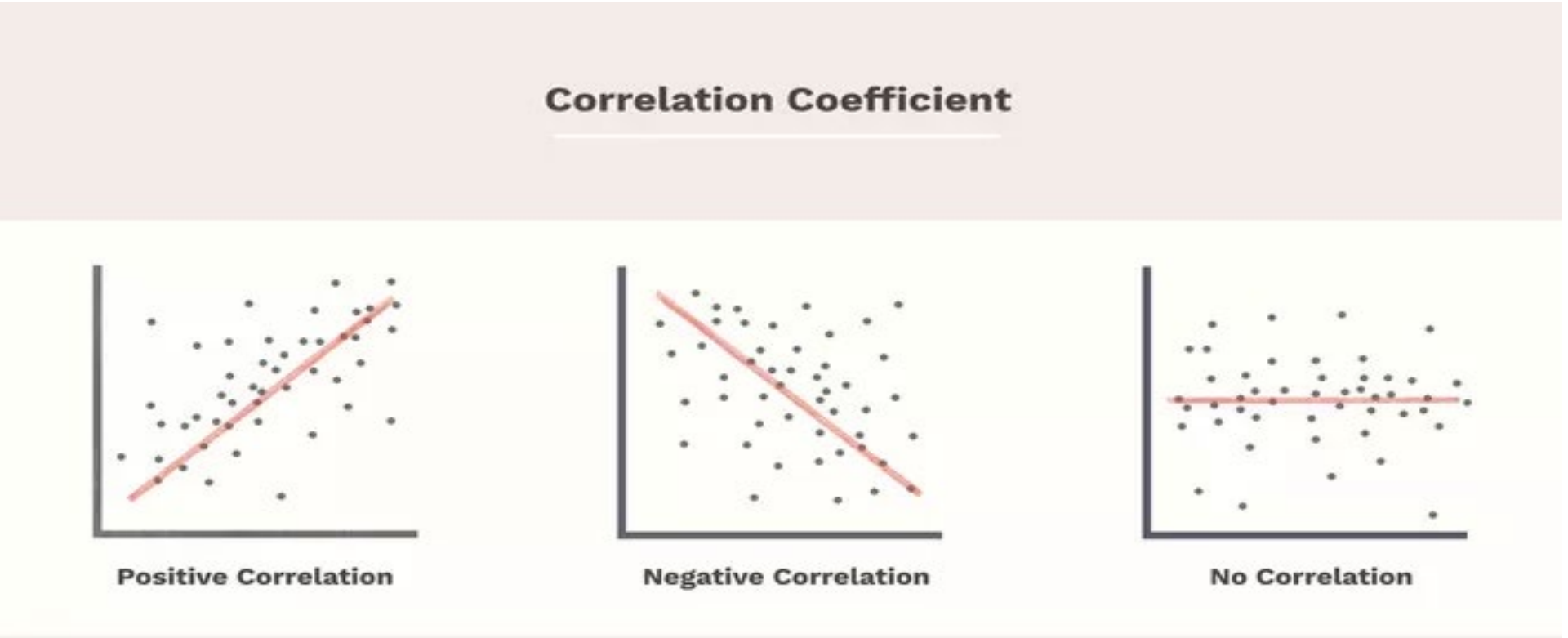
ECOLOGICAL STUDIES (CORRELATION STUDY)

e.g. there were cigarette consumption rate of 1500 per capita /year in a city in 1935 (lung cancer rate 10/100,000) which raised to 3500 in 1955 (LCR: 40/100,000).

- This type of studies depends on the correlation between factor and disease occurrence, either (+) ve or (-) ve or no correlation.

Does this mean that every person in the city was a smoker?

CORRELATION RELATIONSHIPS



ECOLOGICAL STUDIES (CORRELATION STUDY)

Disadvantages:

- **Require additional caution in their interpretation.**
- **Ecological fallacy.**
- **Confounding (uncontrolled)**

Advantages:

- **(formulate hypothesis).**
- **simple & quick**

CROSS-SECTIONAL (PREVALENCE STUDY)

- Data collected at a single point in time
- Observation of all of a pop, or a representative subset.
- Describes associations
- **Can you estimate new cases rate in C-S study??**

A "Snapshot"

CROSS-SECTIONAL STUDY (PREVALENCE STUDY)

PURPOSES:

- To examine the health problem frequency/nature.
- To examine the exposure and health problem at the same time.
- Who are affected ?, and how they behave ?
- KAP of people about any health related problem.
- Attempts to assess relationship between exposure and effect (comparative cross-sectional studies).

- a cross-sectional study can be either ***DESCRIPTIVE, or ANALYTICAL*** according to its purpose.
- If the information collected is purely of a **descriptive nature**, this is a *DESCRIPTIVE CROSS-SECTIONAL STUDY*.
- If data are **analysed so as to demonstrate differences** this is an *ANALYTICAL CROSS-SECTIONAL STUDY.*

CROSS-SECTIONAL STUDY

Advantages:

- cheaper, easier and faster
- measure burden of disease (prevalence not incidence) ??
- identify high risk group. As a baseline for future analytic study
- Hypothesis formulation study.
- Start with reference population so generalization possible

CROSS-SECTIONAL STUDY

Disadvantages:

- Can show association only but NOT CAUSATION –
- No temporal sequence, Chicken-egg dilemma;
- Not good for studying rare diseases or diseases with short duration; also not ideal for studying rare exposures.
- Interpretation requires caution regarding potential association of duration of disease with exposure status (Survivors BIAS)
- Other Possible biases - selection, memory or recall.

OTHER OBSERVATIONAL DESCRIPTIVE STUDIES

- Biometric study
- Registry based Study
- Systematic review
- Meta-analysis

Can descriptive studies test hypothesis??

ANALYTIC STUDIES
all types:

Purposes:

- Are studies used to test hypotheses (Hypothesis testing studies).
- And to measure the magnitude of the association

OBSERVATIONAL ANALYTIC STUDIES

- **Case control study: disease → exposure**
- **Cohort study: exposure → disease**
- *Exposure & disease* can be the Independent or Dependent variable according to the study used.
- **Comparative cross sectional studies.**

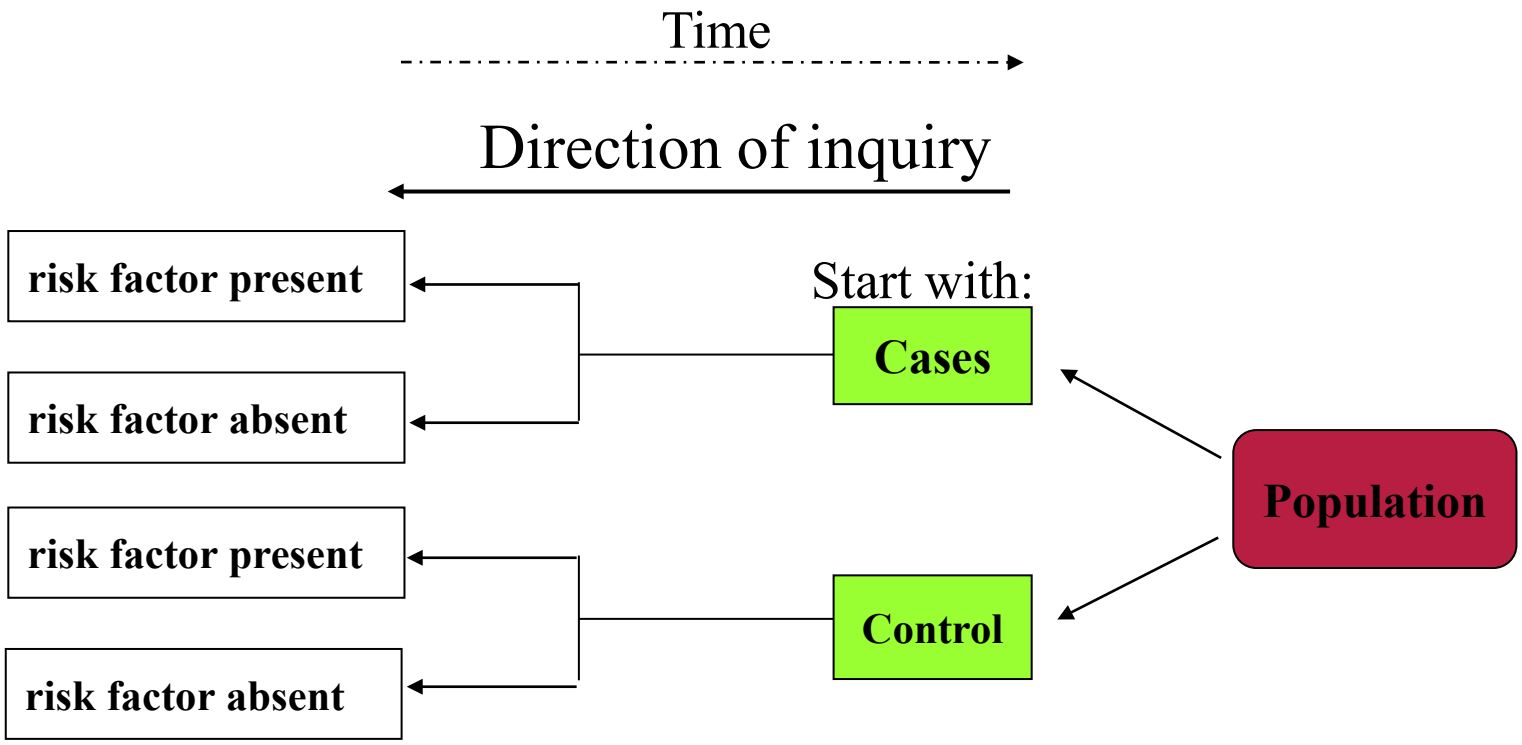
CASE-CONTROL STUDY

A type of observational analytic studies, where the subjects are selected on basis of “whether they do have the disease (*cases*) or they do not have the disease (*control*) under study”.

- The 2 groups then compared for the proportion of having a previous exposure (s) or characteristic of interest.

Incident cases (newly diagnosed cases) are preferred .. Why?

- **Design of a Case - Control**



CASE-CONTROL STUDIES

Advantages:

- Is relatively quick and inexpensive
- Is optimal for the evaluation of rare diseases.
- Can examine multiple etiologic factors for a single disease.

Disadvantages:

- Is inefficient for the evaluation of rare exposures
- Cannot compute incidence rates. ***Why??***
- Is particularly prone to bias, selection and recall bias.