



### - What is a research design?

- It is a framework for conducting the research project. It details the procedures necessary for obtaining the information needed to solve a research problem.

### - Types of epidemiological study:

- **Observational studies:** in which there is no intervention (e.g. it allows nature to take its course and the investigator does not intervene). These studies are further classified into:

- ✓ Descriptive studies: they precede analytic studies and they are used to identify any health problems. In addition, they are concerned with characterizing the amount and distribution of disease within a population.

#### ❖ Case report:

- Detailed objective presentation of single case or event (generally reporting a new unique finding) such as:

- ✚ Appearance of a new disease.
- ✚ Unusual presentation of a disease.
- ✚ Unexpected new therapeutic effects/adverse events.

- Advantages:

- ✚ Representing the first evidence of the new event.
- ✚ Generates hypothesis and defines issues for further studies.

- Disadvantages:

- ✚ Not generalizable.
- ✚ Does not provide cause-effect relationship.

#### ❖ Case series:

- Detailed objective presentation of group of patients (generally reporting new and unique condition).

- Advantages:

- ✚ Initial form of evidence.
- ✚ Generates hypothesis and defines issues for further studies.

- Disadvantages:

- ✚ Not generalizable.
- ✚ Does not provide cause-effect relationship.

#### ❖ Ecological studies:

- The unit of observation and analysis is a group most often defined geographically. Analysis may involve: incidence, prevalence or mortality data.

- Advantages:

- ✚ Suggests avenues of research that may be promising in exploring causal relationship.

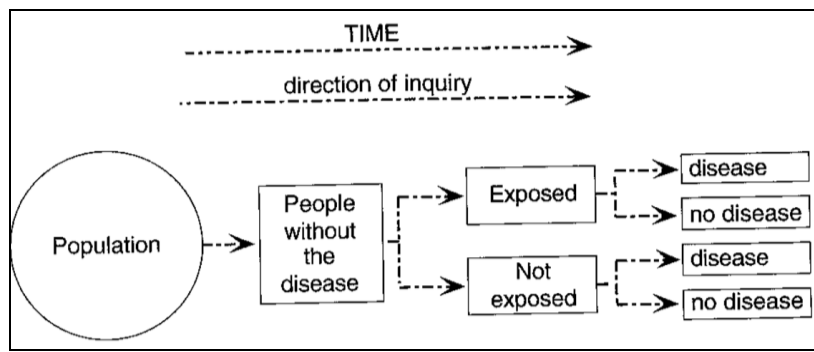
- Disadvantages:

- ✚ Primary analytical feature of an ecological study is that we don't know the joint distribution of study factors disease within each group.

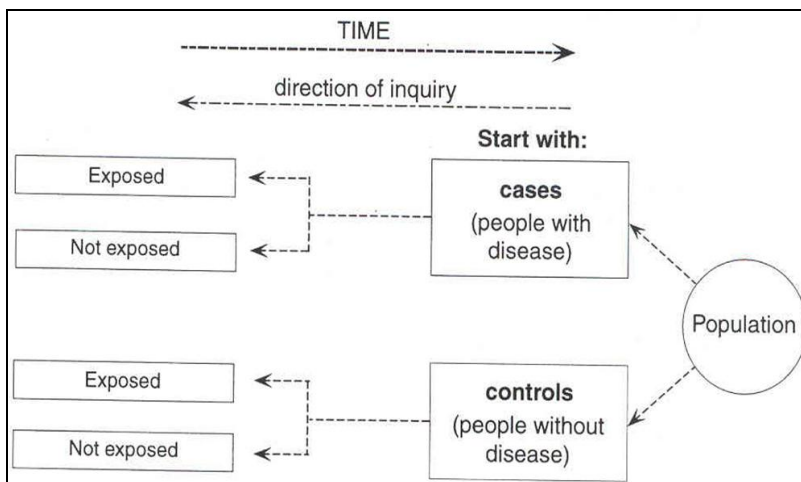
- ✓ Analytic studies: they are concerned with the determinants of a disease and include:

#### ❖ Cohort:

- In this study, exposure is known for all subjects at the beginning of the follow-up period. Population at risk of developing the outcome event is followed for a period of time.



- Cohort study is of two types:
  - ✚ Prospective (current): in which data on exposure are collected prior to the occurrence of disease and subjects are followed up over time to observe occurrence of a disease.
  - ✚ Retrospective (historical): past exposure data are collected for a defined cohort using historical records.
- Advantages:
  - ✚ Measuring incidence. Therefore, there is a direct estimate of the risk.
  - ✚ A range of outcomes can be studied.
  - ✚ Providing evidence about lag-time between exposure and disease.
- Disadvantages:
  - ✚ Expensive.
  - ✚ Not suitable for studying rare diseases.
  - ✚ Selection bias.
  - ✚ Large size.
- ❖ *Cross-sectional:*
  - It involves a health survey of a group of individuals in a specified population at an instant of time (في لحظة من الزمن).
  - Used to: estimate the prevalence of a disease in a population.
  - Advantages:
    - ✚ Inexpensive.
    - ✚ Can be completed within a short time frame.
    - ✚ Does not involve a follow-up period.
  - Disadvantages:
    - ✚ Unable to determine if exposure preceded or resulted from the disease.
    - ✚ Not appropriate for studying rare diseases or those with short duration.
- ❖ *Case-control:*
  - It is a backward study which compares patients (those with a disease) with controls (persons who are free from the disease). In this study you compare the past exposure to 1 or more potential risk factors.



- Advantages:
  - ✚ Inexpensive.
  - ✚ Relatively a short study period.
  - ✚ Used to study rare diseases.
  - ✚ Used to investigate several potential etiological factors.
- Disadvantages:
  - ✚ Inability to provide direct estimate of the risk.
  - ✚ Susceptible to recall bias.
  - ✚ Uncertainty of the exposure-disease relationship.

- **Experimental studies:** in which there is an attempt to change a variable in one or more group of people relevant to the outcome and they include:
  - ✓ Field trials: in which subjects are free from the disease. Example: Salk vaccine field trial. This type of study is expensive.
  - ✓ Community intervention trials: in which interventions are done on a community-wide basis (class rooms, residential building, army units... etc).

Water supply <b>A</b>	Water supply <b>B</b>
<i>Observe occurrence of disease for a specific period of time</i>	
Randomly assign intervention	
Add chloride	Do nothing
Dental caries	Dental caries

- ✓ Clinical trials: planned experiment which involves patients and is designed to elucidate the most appropriate treatment, new drug, new surgical procedure or alternative approach to patient management for future patients with a medical condition.

❖ *Randomized clinical trial:* it is the gold standard of clinical and epidemiological studies. They are intervention studies which choose a group of patients who are suitable for one or more type of drug intervention. Disadvantages include:

- Cost (since large number of patients are needed with prolonged follow-up).

