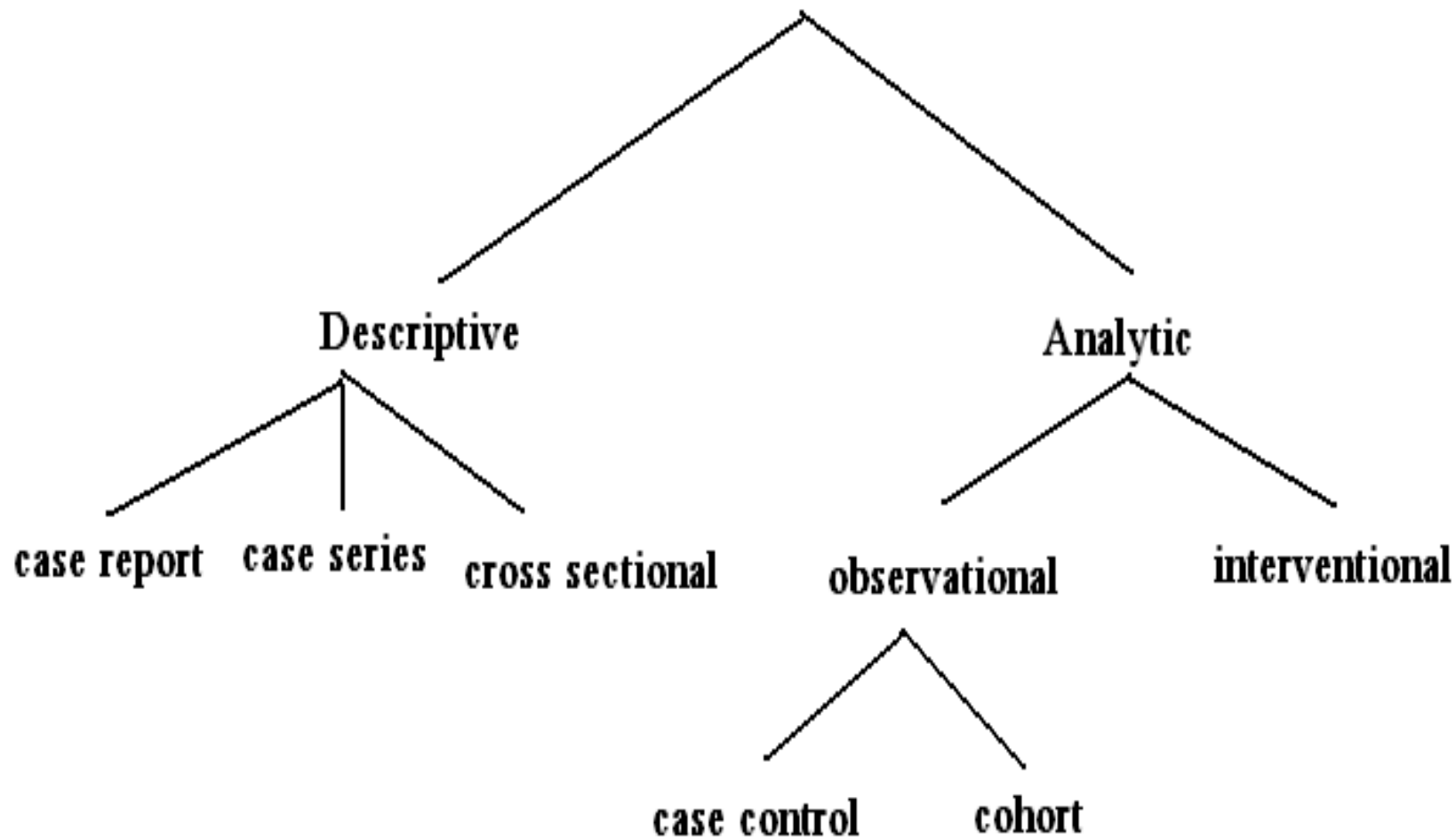


Study Design

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Study Design



- **Descriptive Study:**

- This study describe the occurrence of disease in terms of (place, person, time) or (host, agent, environment) depending on 1. Characters of exposure (time, dose, approach) and 2. host susceptibility.

It is the first step for further studies, this step enables us to :

1. Develop or formulate a hypothesis which can be tested by the analytic studies, and
2. Identify the high risk groups.

- **It has 3 main types:**

A- Case report:

- This is the first step in descriptive study which describes the clinical observation that are interesting or any abnormal variation in a disease. It brings our attention to new or rare diseases and relates between them to find a conclusion it is easy, simple, not time or effort consuming (advantages), but we can't generalize the findings on population (disadvantage).

B- Case series:

- This is the second step where we study a group (series) of cases which have similar abnormal clinical findings enabling us to present clinical pattern to identify the characteristics of diseases. It is simple, not time, effort or money consuming and can (recognize new disease) (advantages) on the other hand it can't be generalized to the population (with difficult risk estimation) (disadvantages).
- e.g. In 1979, Kaposi's sarcoma was discovered in a young male this sarcoma happens in the elderly, so this finding was strange. then the case was put on a case report. few years later, similar cases were discovered. So a case series study was done and reached a conclusion in 1984 that Kaposi's sarcoma happens in young males who are addicts and homosexual and this led to the foundation of AIDS.

C- Cross- sectional study:

- Photograph study: prevalence study, or snap shot. This study describes the health problems in the whole population or in a sample from it (which should be representative) in a specific point or a short period of time to study the exposure, distribution and the occurrence of disease, and to formulate a hypothesis. It is not expensive, not time or effort consuming and can measure the prevalence and many variables at the same time (advantages).

- It's disadvantages include:
 1. It is not representative to the whole population and can't be generalized to the whole population.
 2. It can't measure the risk.
 3. Selective survival: due to the exclusion of deaths from the study, while it is possible that many deaths could be attributed to the health problem under study.
 4. It carries bias (memory) or patient bias under or over estimation and interviewer bias which needs documents to be avoided.
 5. Chicken - egg dilemma: this is explained by the fact we don't know who affects the other the disease or the factor e.g. logically, we know that anxiety can cause angina pectoris, but it is possible that the patient becomes anxious when he knows about his disease.
- Note: the descriptive studies enable us to formulate a hypothesis but it can't test it.

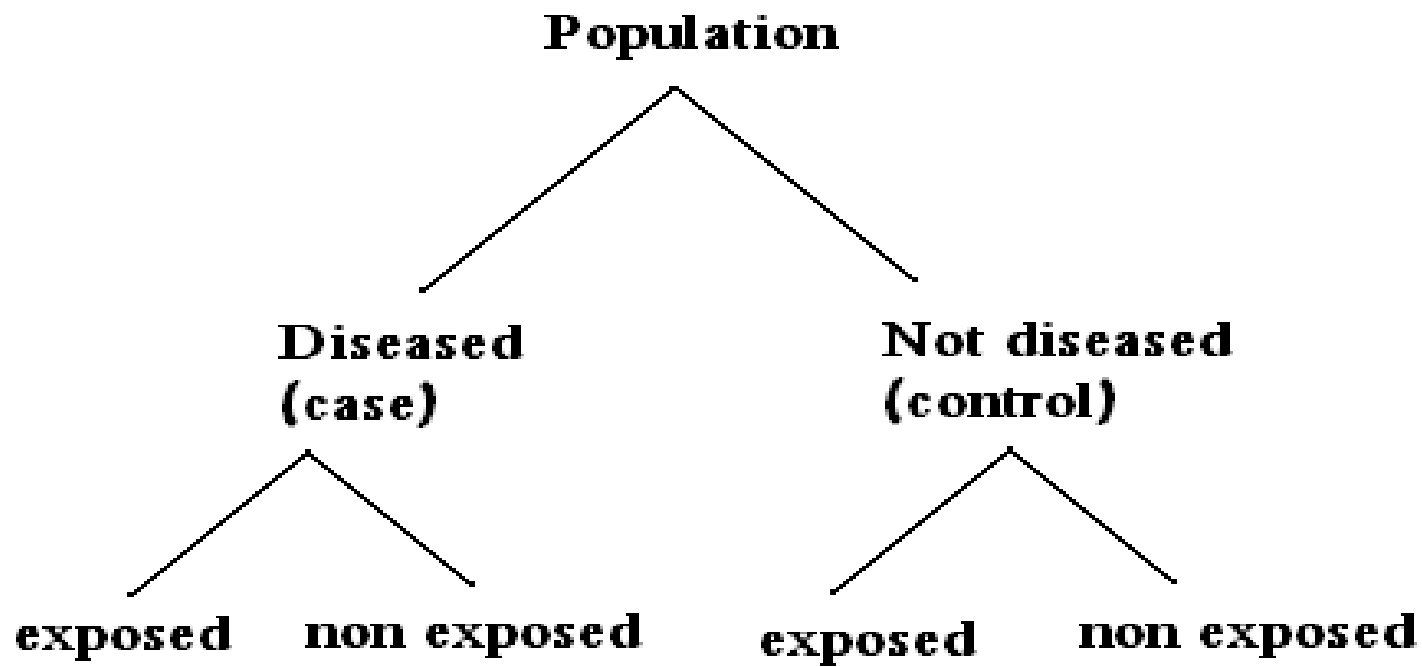
- **Analytic Studies**

- These studies go beyond the identified facts towards testing and analysis of them. They are important in testing the hypothesis which was formulated in the descriptive studies. The factor and the disease can be dependent or non dependent according to the approach of the disease they are of 2 types:

- **A. Interventional:** will be discussed later

- **B. Observational:** Here we just observe what happens recording the disease and exposure but we don't ever interfere in the study. It is of two types:

- **Case – Control:**
- Here, the subjects are selected on the base of absence or presence of disease the study follows the following scheme:



- e.g. for people with CA lung (diseased) and people with no CA lung (control), we ask them if they were smokers (exposed) or not smokers (non-exposed) to determine the state of exposure for the diseased and the non-diseased people. This is done mainly by odds ratio (OR).

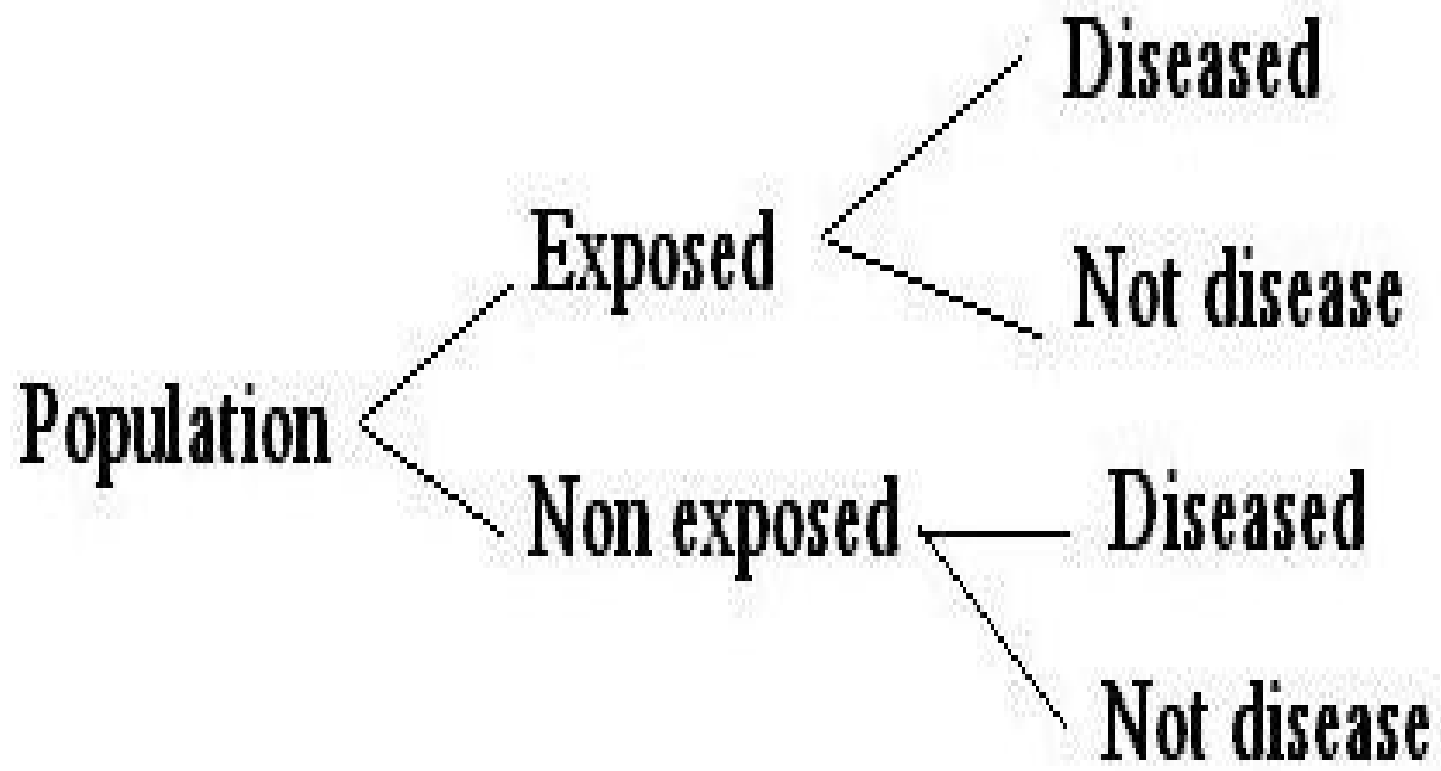
- **Advantages:**

1. Quick, easy, not expensive and not time consuming.
2. Useful in rare diseases.
3. We can get odds ratio from it.
4. Can support (but not prove) the hypothesis.

- **Disadvantages:**

1. Bias.
 2. Not representative (because we study the diseased people).
 3. Cannot measure the incidence or RR, i.e. it cannot prove the hypothesis, but can test it only.
 4. The presence of confounders, because the disease occurred in the past.
- **Note:** for each case – control study, the control must be higher than the cases.

- **Cohort study :**
- Also called “**Movie Picture**” this study follows the sample exposure for wards to reach the disease. The subjects are selected depending on the bases at absence or presence of exposure (not the disease). The dependent part here is the diseased group and the independent part is the exposure.



- It is more accurate than the case control study.

- **Types:**

- **1- Retrospective cohort:**

- This type investigates the person known to have the disease, so it is more important in the study of long latency period diseases.

- **2- Longitudinal cohort:**

- Or known as (prospective, follow up, incidence) cohort. This is the most common, it studies the person free of disease so it is more accurate, but time consuming and can measure the incidence.

3- Historical prospective study:

- Here, we study an already exposed patient and continue to follow him up until reaching a conclusion.
- e.g. to study the association between smoking and CA lung, CA lung develops after 15-20 years from the exposure(beginning of smoking),so:
- Retrospective Cohort: we study people with CA lung and people free of it and study their history of smoking from 20 years ago.
- Prospective Cohort: we study smokers and non-smokers for 15-20 years and note the CA lung development among them.
- Historical Cohort: we study smokers and non-smokers from 10 years and continue to follow up them for 15-10 years to note the CA lung cases among them .

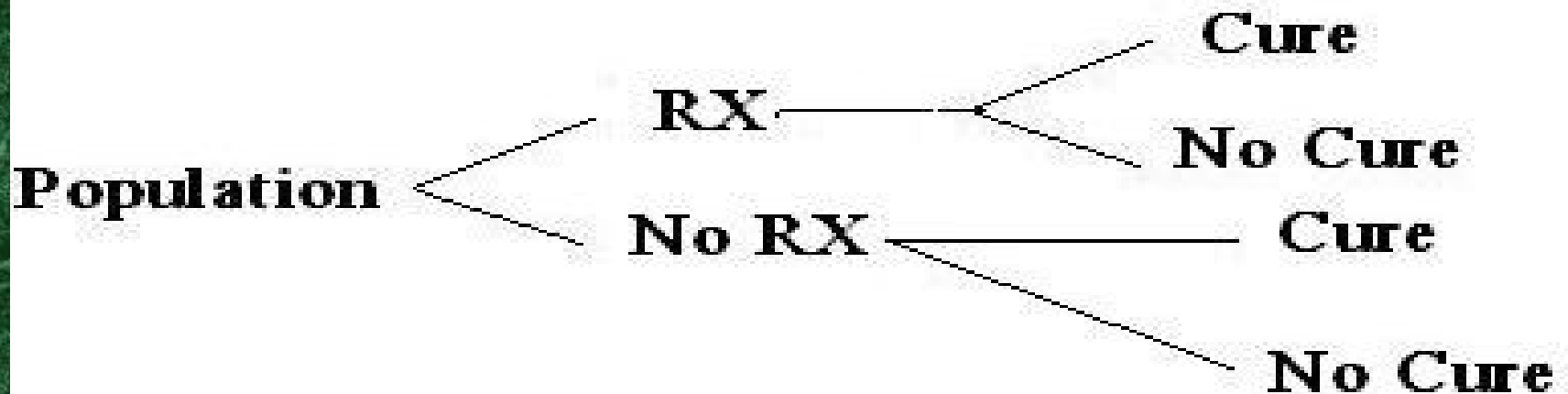
- **Advantages:**

1. Very accurate.
2. Studies more than one effect for a single exposure e.g. studies CA lung, CA stomach, DU for smoking.
3. Measures the incidence and RR and studies the strength of relationship between exposure and disease i.e. studies the causation.
4. Suitable for rare exposures (not rare diseases).
5. Can measure the time interval between exposure and study clearly.

- **Disadvantages:**

1. Time, effort and money consuming.
2. Not suitable for diseases of low incidence because non or few of the diseased group will show the disease.
3. Non responsiveness and attrition bias of the sample, so we can't control the study. This can be controlled by a form of "project".
4. Depends on the personal and researchers availability.

- **Interventional Study:**
- Previously called “experimental study” this is a high quality type of cohort study, where the investigator himself allocates the exposure but here we don’t observe only but we interfere in the study (by drugs, surgery, immunization ... etc)



- **Types:**

- 1- Therapeutic trial:**

- In which we interfere in a new form of therapy, either medical or surgical the medical therapy has 3 main approaches:
 - a) Give a new drug to test its efficacy and side effects in comparison to an old one, e.g. in hypertension, test atenolol (new) against aldomate (old).
 - b) Compare a new drug against placebo.
 - c) Test the new drug effect before and after giving it to the patient.

- **Preventive trial:** it is either
 - a) On the base of the individual, e.g. immunization.
 - b) On the base of community e.g. adding fluorine to water to prevent dental caries and adding iodine to the salt to prevent endemic goiter, this process is called “**fortification**”.

- **Advantages:**

1. High quality and accuracy.
2. It can provide a degree of assurance about the validity of the results. This is not possible in any observational study.

- **Disadvantages:**

1- Time, money and effort consuming.

2- Chance factor:

- Which can be avoided by randomization and increasing the sample size.

3- Subjectivity bias:

- Where the researcher tends to style the method or results. This can be avoided by masking (blindness technique) which is either:

- a) Single: the patient does not know the drug he is taking.
- b) Double: the patient and the doctor does not know the drug.
- c) Triple: the patient, the doctor and researcher does not know the drug.

4- The presence of confounders:

- This can be avoided by matching i.e. the drugs given should be similar e.g. in size, form and color and people venter study should be at the same age and state, and they must be different only in the factor under study (i.e. patient and control).

5- Ethics:

- a) We must be sure that the drug or the procedure is not harmful.
- b) We must inform the volunteer about the study and take his permission.
- c) There must be a sufficient doubt about the particular agent to be tested to allow withholding it from half the subjects and at the same time there must be sufficient belief in the agent potential justice in exposing the remaining half.
- d) Feasibility should be considered before a belief gets wide spread.

END