Public Health
Prevent. Promote. Protect.

Epidemiological studies II
Cohort Study
L13

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Cohort studies

- In cohort studies, the starting point is people who are free from the disease. Such people are identified and followed up for a defined period of time (prospective).

- During the follow up, new cases or deaths that result from the disease under study are recorded and related to different levels of exposure to risk factors (exposure) under evaluation.

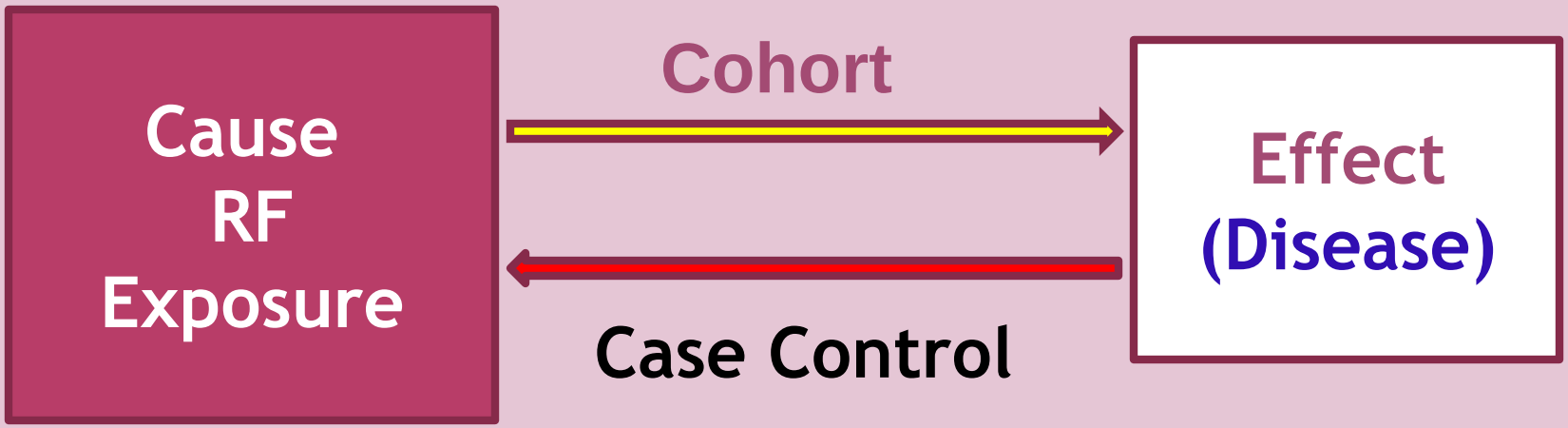
- We always start with at least two groups: the study cohort which consists of those:

1. exposed to the risk factor and
2. the control cohort which consists of those not exposed to the risk factor.

:Cohort study has 2 types

- **Prospective** cohort study: All data will be collected in the future

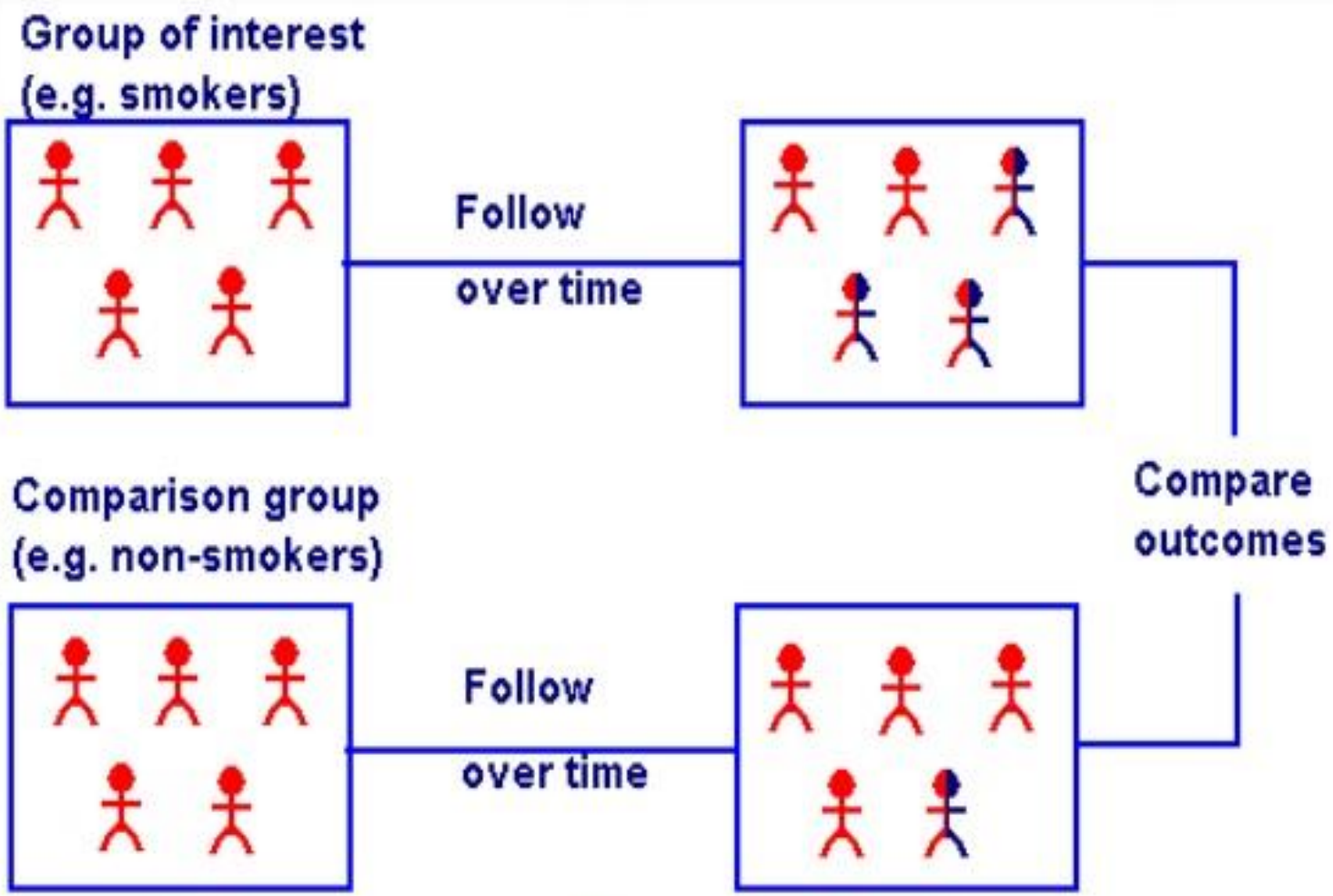
- **Retrospective** prospective study: where part is carried out retrospectively by collecting existing data then the cohort is followed till the outcome under study is developed.



Concept of a cohort

In epidemiology the word cohort is defined as a group of people who share a common characteristic or experience within a defined period of time (e.g. age, occupation, exposure to drug, vaccine, pregnancy, birth or marriage cohorts).

The comparison group may be the general population from which the cohort is drawn or may be another cohort of persons thought to have had little or no exposure to the substance in question.



Cohort Studies

Elements of a cohort study

1- Selection of the study subjects:

General population (when exposure or the cause of the disease is fairly frequent in the population. The cohort residing in the same geographical area as in (Framingham study)

Selected groups as professional group

Exposure group: cohorts selected with special exposure to physical, chemical or other disease agents.

2- Obtaining data on exposure from:

- Cohort members, questionnaire through personal interviews, or mailed questionnaire in large cohorts.
- Review of records: dose of radiation, number of surgeries, details of medical treatment,
- Medical examination or special tests e.g. BP measurement, serum cholesterol……. etc.

3- Selection of comparison group:

- **Internal comparison:** the same cohort that enters the study may be classified into several comparison groups according to the degree of exposure (smoking, cholesterol) before the development of the disease in question.
- **External comparison:** if all of my cohort is exposed to the risk factor (radiologist, so we compare with ophthalmologist, this would make external comparison).

- Comparison with the rates of the general population e.g. mortality experience of the exposed group is compared with mortality experience in the general population (comparing the mortality rate of asbestos workers with the mortality rate in the general population).

4- Follow up:

- Periodic medical examination
- Reviewing physicians and hospital records
- Routine surveillance of death records
-Mailed questionnaires
-Telephone calls
-Home visits.

5- Analysis of Cohort study:

The data obtained are analyzed in terms of :

A. **Incidence rate** of occurrence of outcome among exposed and non exposed groups.

B. Estimation of risk

Benefits of cohort study:

-It is of value when the exposure is rare.

-Can examine multiple effects of single exposure .

-It estimates :

- Incidence of disease among exposed & non exposed.
- Relative & attributable risk.
- Dose response relationship .

-It allows testing the hypothesis.

- No selection bias since the exposure is assessed prior to the occurrence of the disease, the outcomes could not influence the selection of the exposure.

The limitations of the prospective cohort study:

- Not suitable for studying rare diseases.
- Loss of experienced staff, loss of funds.
- Change in the environmental factors.
- Change in standard diagnostic methods or diagnostic criteria of diseases.
- The study itself may alter the participants behavior.
- Attrition problem:Drop-outs.
- Ethical problems.
- Expensive.
- Time consuming (20-30 years in cancer studies).

Example

A study was carried out to ascertain the relationship of parental smoking to the risk of acute respiratory infection among children aged less than five years.

A total of 800 children of smoking parents and 1200 of nonsmoking parents were followed up for six months.

During the follow up period, 592 of the first group and 636 of the second group developed at least one attack of acute respiratory infection.

Do these results suggest that parental smoking predisposes children to acute respiratory infection?

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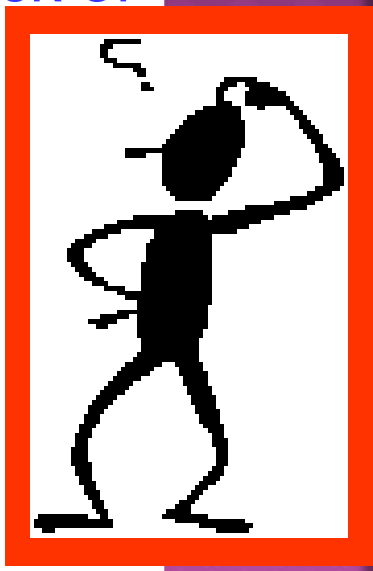


First construct 2x2 table

Exposure to Risk Factor	Develop a disease	Did not Develop a disease	Total
Exposed (Smoker parents)	592 a	308 b	800 a + b
Non Exposed (Non Smoker parents)	636 c	564 d	12 00 c + d

a= individuals exposed to the risk factor and develop the disease

b= individuals exposed to the risk factor and do not develop the disease

c= individuals do not expose to the risk factor and develop the disease

d= individuals exposed to the risk factor and do not develop the disease

The analysis

The first step is to calculate the incidence rate of infection in the two cohorts.

Incidence rate among children exposed to parental smoking

$$= \frac{592\ (a)}{800\ (a+b)} \times 1000 = 740/1000$$

Incidence rate among children not exposed to parental smoking

$$= \frac{636\ (c)}{1200\ (c+d)} \times 1000 = 530/1000$$

Interpretation

It is clear that the incidence rate of acute respiratory infection is greater among the exposed group than the non exposed group

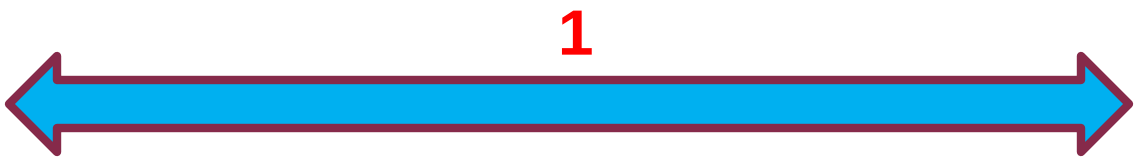
The second step is to measure the strength of association between parental smoking and infection by calculating the relative and attributable risk.

$$\text{The relative risk (RR)} = \frac{\text{Incidence rate among exposed}}{\text{Incidence rate among non exposed}}$$

$$= \frac{40}{530} = 1.4$$

Interpretation

This means that the risk of infection among children exposed to parental smoking is 1.4 times greater than the risk of infection among children not exposed to parental smoking.



Protective **No relation** **Risk**

In addition to the relative risk, we also measure the attributable risk which represents the fraction of risk that could be attributed to the exposure under study.

Attributable risk = Incidence rate among exposed – incidence rate among non exposed.

AR = 740 – 530 = 210 / 1000 (if parental smoking is removed the incidence of infection is decreased in nearly 210 /1000).

$$\text{Attributable risk reduction} = \frac{\text{AR}}{\text{I among Exp}} \times 100 = \frac{210}{740} \times 100 = 28.3\%$$

Sources of controls in cohort studies

In **cohort studies** the main sources are:

1. Built in comparative cohorts as for example in studying the relationship of lung cancer to smoking, people may be categorized into subgroups of heavy smokers, moderate smokers, light smokers and nonsmokers

2. Relatives and neighbors.

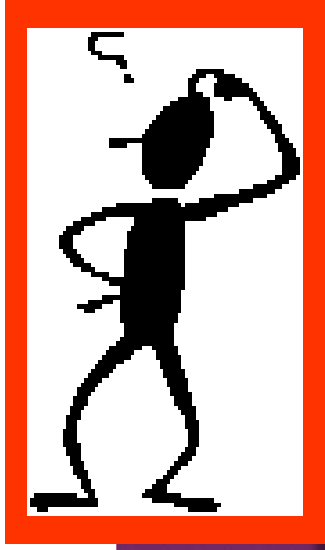
3. The total population provided that the level of exposure is ascertained at population level at the start of the study.

4. Special occupational groups.

Comparison of case – control and cohort studies

Item of comparison	Case-control	Cohort
No. of subjects	Small	Large
Time	Short	Long
Cost	Lower	Higher
Organization	Easier	More difficult
Interpretation of results	More difficult	Easier
Usefulness for rare disease	Useful	Not useful
Usefulness for risk measurement	Less useful	More useful
Usefulness for causal criteria	Less useful	Very useful
Risk to subjects	Usually none	Risk of not removing exposure

Which Kind of Study is Better?



- Case-control studies are more common, but cohort studies are generally more convincing.
- Case-control studies are more common than cohort studies because they are faster and cheaper.

Cohort studies are more convincing for two reasons:

1. they provide much better opportunity to establish a cause-effect relationship because they begin with the exposure (cause) and move forward in time to the disease (effect).

In contrast, case-control studies begin with the disease (effect) and look back to the exposure (cause). It is not always clear that the identified cause actually did come first.

2. case-control studies are more prone to certain study design problems, such as bias or chance .

But cohort studies have their own drawbacks:

1. they are very expensive.

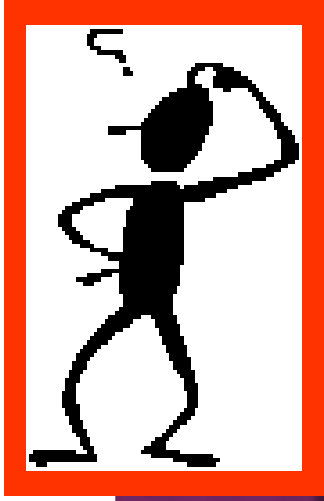
2. they take a long time (because they start with well people and wait for them to get sick).
3. they are difficult to conduct properly because study subjects tend to drop out of the study over time.

For the reason of drop out , the denominator is calculated according to the no. of years of follow up for each person. This is called person –year.

Person –year:

The number of people in the study and the amount of time each **person** spends in the study.

Experimental Studies



- The goal of public health as well as clinical medicine is to essentially modify natural history of disease to decrease morbidity and mortality.

- The question then becomes, how do we know which preventive and therapeutic measures are most effective to achieve this goal?
- To do that, researchers carry out formal studies. Specifically experimental studies for the purposes of this presentation to determine the value of various measures.

- Experimental studies sit at the top of the hierarchy of epidemiologic study design and produce the most valid results but come at a very high cost.

- It can be viewed as prospective cohort study.

Advantages

- Gold standard of epidemiological research.
- High status and validity and can pick up small and modest effects.
- James Lind identified symptoms of scurvy among sailors at sea after as little as a month.
- Conducted early experimental study on treatment of scurvy in mid-1700's among British sailors.
- Small sample size.
- Group eating oranges and lemons were fit for duty in 6 days

Potential Uses

- Evaluate new drugs and other treatments for diseases.
- Evaluate new medical and health care technology.
- Evaluate new screening programs or techniques
- Evaluate new ways of organizing or delivering health services (e.g. home v. hospital care following myocardial infarction)

Ethical points must be considered:

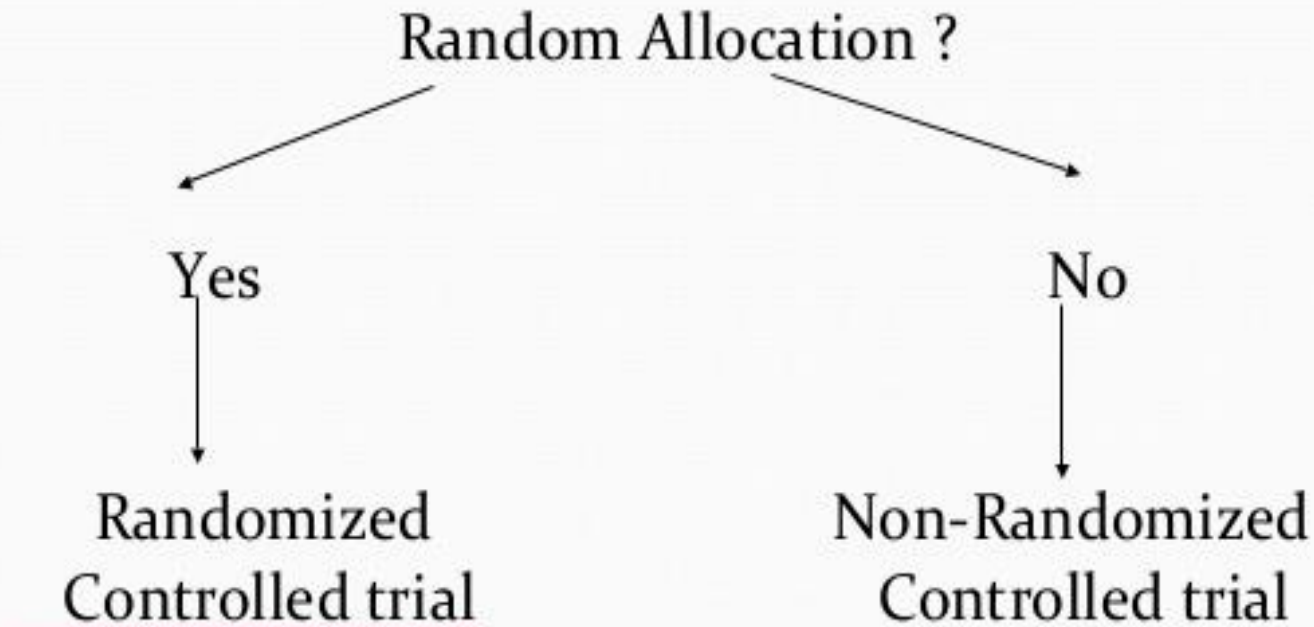
- it should have beneficial effect to patients, not to harm anyone by intervention
- participants should know what the experiment is and have the right to refuse
- if any unplanned complications occur to any participant he should be excluded from the trial and treated.

Types of experimental studies:

a) Clinical trials:

- It is usually used to assess efficacy of a new line of ttt (a new drug for example) or to compare 2 types of ttts: surgical or medical.
- Diseased subjects are randomly allocated into 2 groups, "ttt" group (who are given the new drug) and "control group" (who are given the usual ttt or no ttt in placebo).
- Results are assessed by comparing health improvement of the 2 groups at end of trial.
- Example: surgical or medical treatment of peptic ulcer

EXPERIMENTAL STUDY



RCT

Advantages and Disadvantages of Experimental Studies

Advantages

- Prospective direction
- Ability to randomize subjects
- Temporal sequence of cause and effect
- Can control extraneous variables
- Best evidence of causality

Disadvantages

- Impossible to control human behavior.
- Ethical Constraints
- Expensive


Thank You!