



Epidemiological studies

Objectives

At the end of the lecture students should be able to:

- 1- Know the main types of epidemiological studies.
- 2-know the main characteristics of these studies.
- 3- Understand the main differences between different types of epidemiological studies.
- 4- Could be able to design a study.



Epidemiological studies can be classified as:

1- Non experimental (**Observational**) studies which include:

A-Descriptive studies and


B-Analytical studies

2- Experimental (**Interventional**) studies.

A- Observational Descriptive studies

1- Cross-sectional surveys or studies.


Is simply a descriptive study which, instead of relying on routine sources of data, uses data collected in planned way from a defined population.



These are based on a single observation usually carried out in a short time.

They are characterized by the following:

- a. They usually measure prevalence of disease or related outcome.
- b. They suggest hypotheses.
- c. They are not useful for diseases of short duration. A single observation may miss cases.


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- d. Their results are difficult to interpret because of seasonal variation and cohort effect.
 - e. They are relatively quicker and cheaper to do.
 - f. Although they are essentially descriptive, they can be modified to estimate incidence of disease and to test hypotheses. A case-control design can be made within the context of a cross-sectional study.

2- Longitudinal or follow up surveys or studies

These are based on repeated observation of the study population over a defined period of time.

They start with a base-line data provided by initial cross-sectional study.


- a. They measure incidence of disease or related outcome.
- b. They suggest hypotheses.

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- c. They are relatively more expensive and difficult to organize.
 - d. They are not useful for diseases of rare occurrence.
 - e. The results are easier to interpret.
 - f. They can be useful to determine seasonal variation of disease and other health related outcomes.

B- Observational ANALYTICAL STUDIES

In analytical studies, the researcher attempts to explore how and why a disease process is initiated or maintained in a given population or place.

In this type of epidemiology, we always use comparative or control groups and we test hypotheses so that they are accepted or not.



To test this hypothesis, two types of analytical epidemiological studies may be used:

I - Case - Control studies

In case-control studies:

1. Both exposure and outcome or disease have occurred before the start of the study.
2. The study proceeds backwards from outcome to cause.
3. Controls are used to support or refute any inference (استدلال)

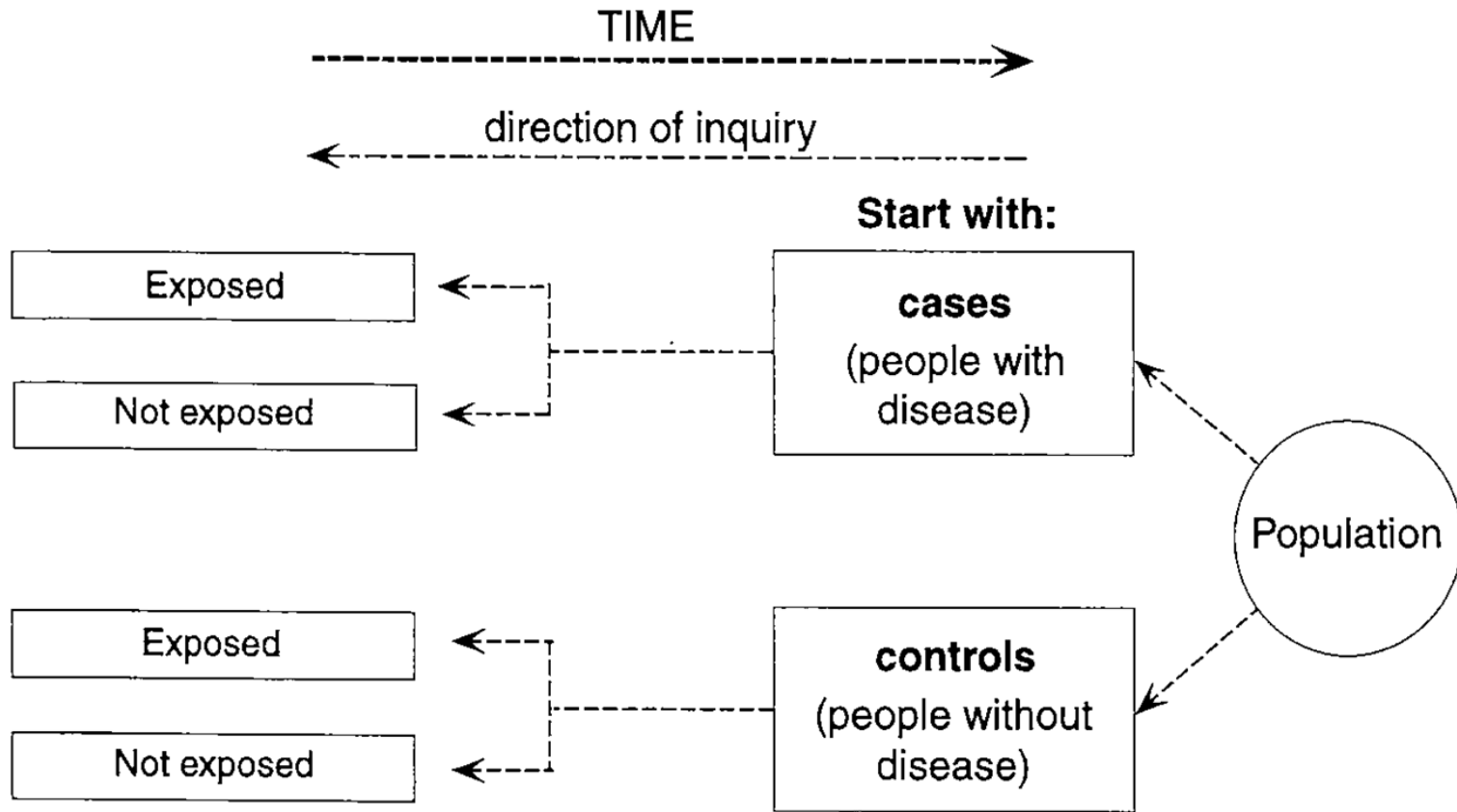
The basic design:

Two groups of persons are studied. The first consists of subjects who have the disease under study at the time of the beginning of the study (**cases**).

The second group consists of subjects who are free from the disease under study (**controls**).

Both cases and controls are preferably similar for age and sex.


Fig. 3.4. Design of a case-control study



2- Cohort studies

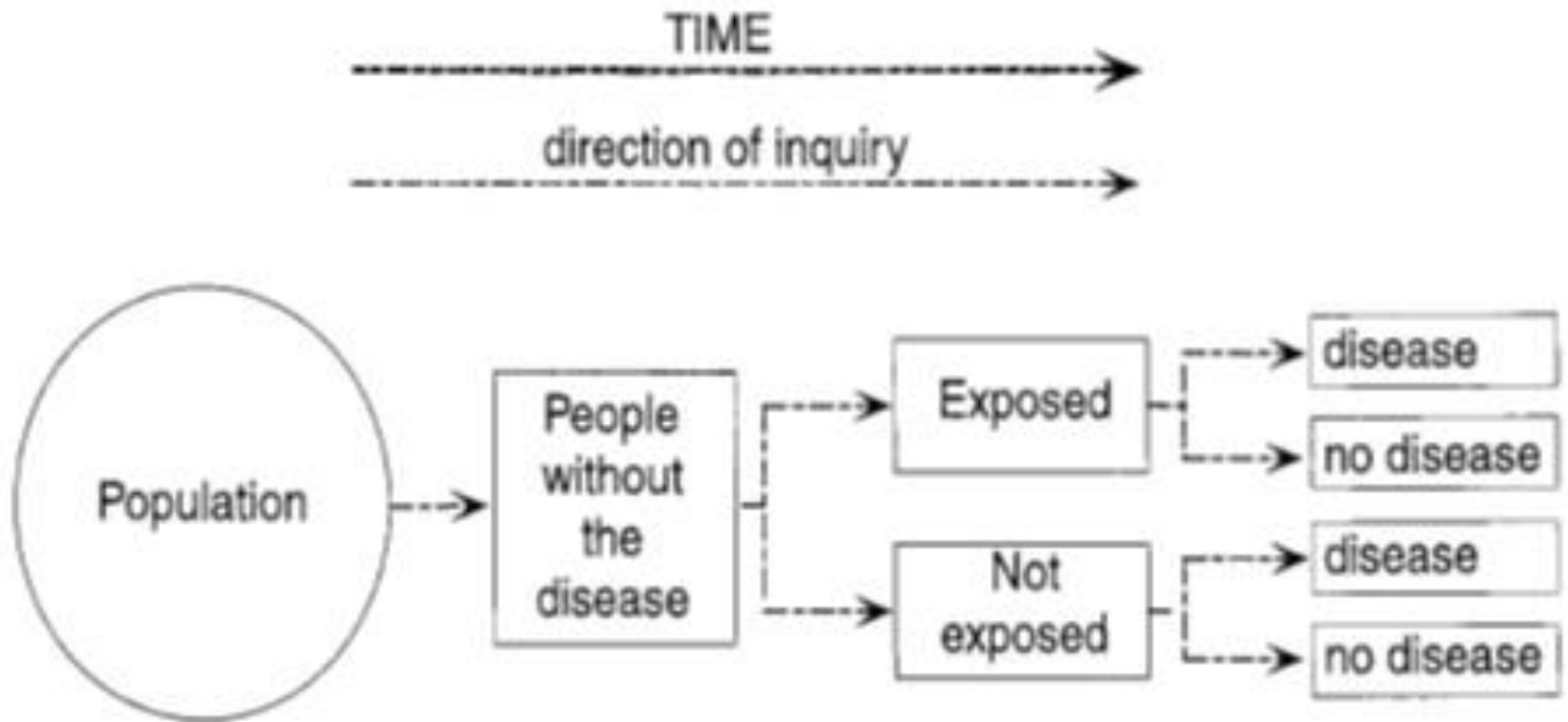
A cohort is a group of individuals who share common characteristics or experience, e.g., birth cohort which represents all live births in one year.

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..



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

Fig. 3.5. Design of a cohort study



Comparison of case – control and cohort studies


<u>Item of comparison</u>	<u>Case-control</u>	<u>Cohort</u>
1. No. of subjects	Small	Large
2. Time	Short	Long
3. Cost	Lower	Higher
4. Organization	Easier	More difficult
5. Interpretation of results	More difficult	Easier
6. Usefulness for rare disease	Useful	Not useful
7. Bias is likely in ascertainment	of exposure	of diagnosis
8. Usefulness for risk measurement	Less useful	More useful
9. Usefulness for causal criteria	Less useful	Very useful
10. Risk to subjects	Usually none	Risk of not removing exposure

2- Interventional studies

Intervention or experimentation involves **attempting to change a variable in one or more groups of people.**

This could mean the elimination of a dietary factor thought to cause allergy, or testing a new treatment on a selected group of patients.

The effects of an intervention are measured by comparing the outcome in the experimental group with that in a control group.



Since the interventions are strictly determined by the study protocol, **ethical considerations** are very **important** in the design of these studies.

Informed consent from study participants is required in almost all circumstances.



Major experimental study designs include the following:

A- Randomized controlled trials using patients as subjects (clinical trials),

B- Field trials in which the participants are healthy people, and

C- Community trials in which the participants are the communities themselves

A- Randomized controlled trials

A randomized controlled trial is an epidemiological experiment designed to study the effects of a particular intervention, usually a treatment for a specific disease (clinical trial).

Subjects in the study population are randomly allocated to intervention and control groups, and the results are assessed by comparing outcomes.

To ensure that the groups being compared are equivalent, patients are allocated to them randomly, i.e. by chance.

B-Field trials

Field trials, in contrast to clinical trials, involve people who are healthy but presumed to be at risk; data collection takes place “in the field,” usually among non-institutionalized people in the general population.

Field trials are often complicated and expensive

Figure 3.8. Design of a field trial

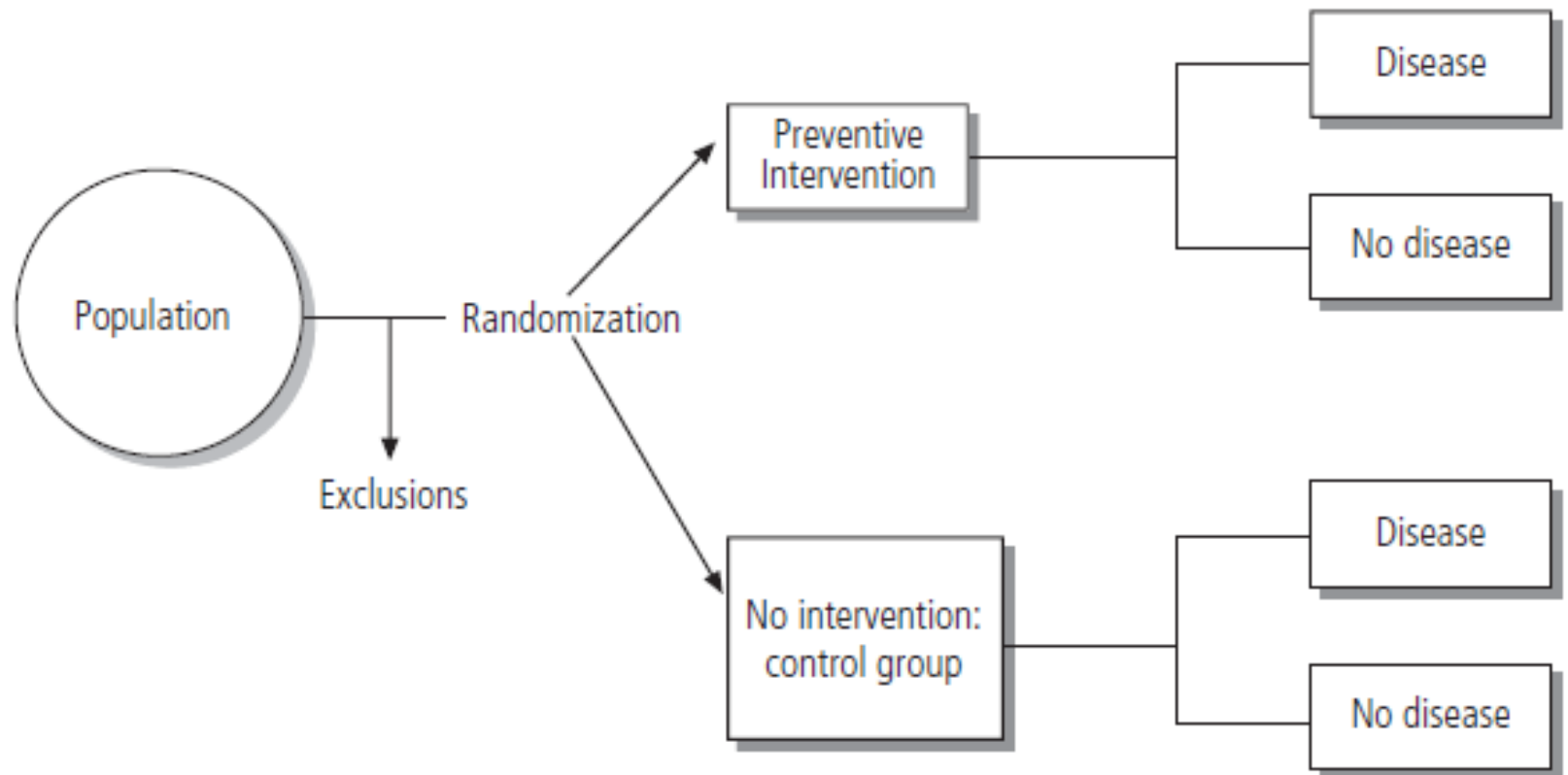
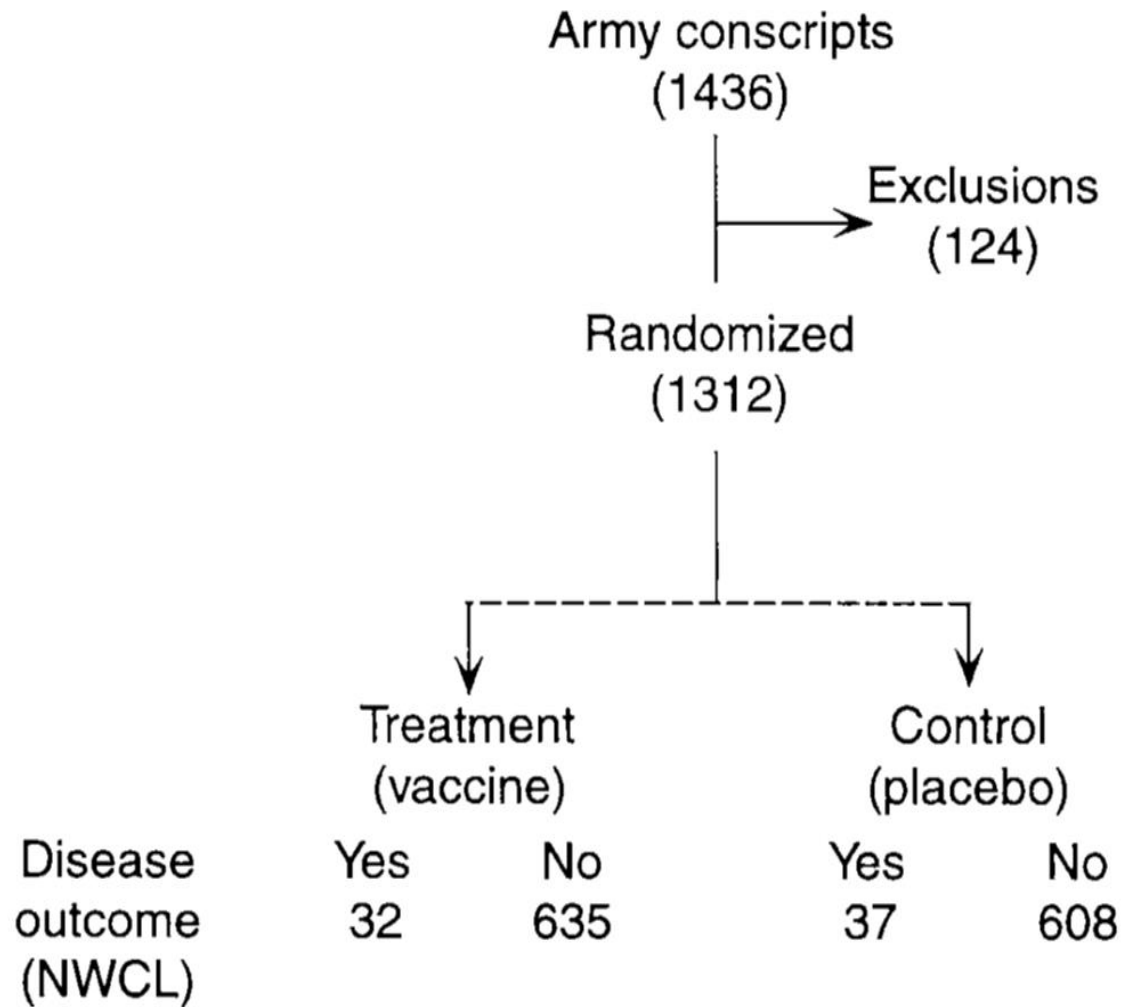



Fig. 3.9. Field trial of vaccine against New World cutaneous leishmaniasis (NWCL)



C-Community trials

In this form of experiment, the treatment groups are communities rather than individuals. This is particularly appropriate for diseases that are influenced by social conditions, and for which prevention efforts target group behavior.

Cardiovascular disease is a good example of a condition appropriate for community trials.



In all epidemiological studies it is **essential** to have a **clear definition of a case** of the disease being investigated and **clear definition of an exposed person** is also necessary.

In the **absence of clear definitions** of disease and exposure, it is very **difficult to interpret the data from an epidemiological study.**

Quiz

- 1- what are the main types of epidemiological studies.
- 2- what are the main characteristics of cross-sectional study.
- 3-what are the main differences between case –control study and cohort study.
- 4- what do we mean by experimental studies and what are the types of these studies.