Epidemiological studies are required to measure the rates of disease occurrence and the associated factors in a population, to make an unbiased comparison of those with or without a disease or risk factor and to make interventions. This is achieved by a good research design.

The type of study design chosen depends on:

- The type of problem
- The knowledge already available about the problem and
- The resources available for the study

Epidemiological studies can be classified as:

Epidemiological studies		
Observational studies(non experimental)		Experimental
Descriptive studies	Analytical studies	
Cross-sectional	Case-control studies	Randomized controlled trials
studies(Survey)		
Longitudinal studies	Cohort studies	Field trials
	Ecological studies	Community trials

<u>1-Observational studies</u>: In these studies the investigator measures but does not intervene, they include:

A-Descriptive studies (Who? What? Where? When?): They are the first phase of an epidemiological investigation. *The main purpose of descriptive epidemiology is to describe the occurrence and distribution of the disease with respect to time, place and person (epidemiologic variables)*. These studies make no attempt to analyze the links between exposure (cause) and effect (disease). This information provides important clues to the causes of the disease and these clues can be turned into testable hypotheses.

1-Cross-sectional studies (prevalence study):

This study measures the prevalence of disease and was called prevalence study. It is based on a single examination at one point in time. They are quick and relatively easy to perform and give a fair idea of the health status of the community, also helpful in assessing the health care needs of populations. It can tell about the distribution of disease rather than its etiology.

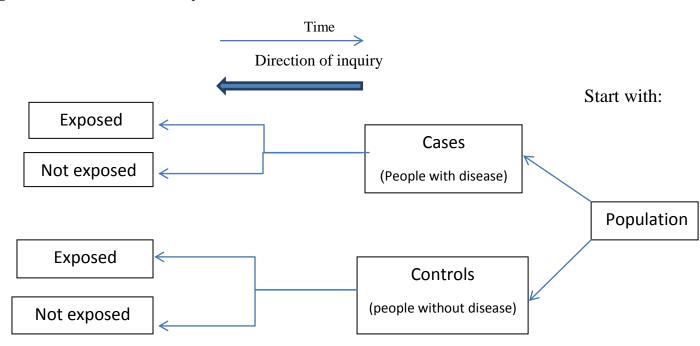
2-Longitudinal studies (incidence study):

In this study repeated examinations are made on the same population over a prolonged period of time in the form of follow-up examinations (frequent cross sectional studies measure trends of disease over a period of time in a given population). By comparing these trends in disease rates with other changes in the society the impact of these changes on disease occurrence can be assessed. E.g. effect of introduction of vaccines. It is used to identify the etiology and risk factors of the disease and for finding out incidence rate.

B- Analytical studies (How? Why?): It is the next step in an epidemiological study .The main purpose of these studies is to *determine the etiology of the disease by testing the hypothesis derived from descriptive epidemiology*. The term 'analytical' implies that the study is designed to establish the cause of a disease by looking for association between exposure to a risk factor and disease occurrence. This study goes further by analyzing relationships between health status and other variables. The most common designs of analytical studies are:

1-Case-control studies: Case control study is useful as a first step when searching for a cause of an adverse health outcome .They are relatively simple and economical to carry out and are increasingly used to investigate causes of disease. It is called retrospective studies since the investigator is looking backwards from the disease(effect) to the cause(exposure). They include people with a disease or other outcome variable of interest(cases) and a suitable group of people unaffected by the disease or outcome variable(control, comparison or reference group). The occurrence of the cause is compared between cases and controls. Data collected more than one point in time thus case-control study is of longitudinal type.

Design of a case-control study:

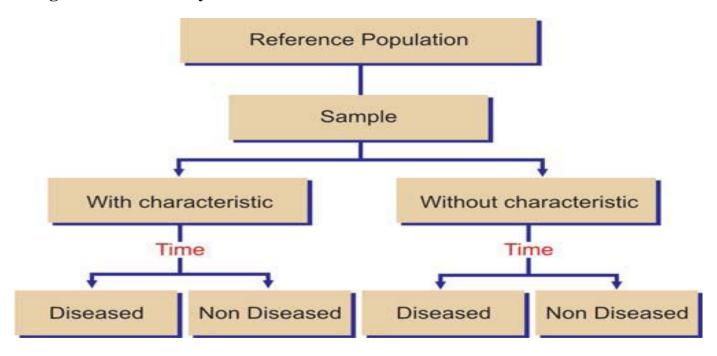


2-Cohort studies (follow-up or incidence study):

These studies begin with a group of people (a cohort) free of disease who share a common characteristic or experience within a defined time period, and this study group is followed up over a period of time to see how the development of new cases of the disease differs among those with and without exposure. That is to say its proceeds from cause(exposure) to effect (disease). It is very expensive because it conducted over a long period of time and sample size must be large to ensure adequate sample after attrition(drop-outs).

Cohort: a group of people who share a common characteristic within a defined time period, e.g. of cohort: age ,occupation, pregnancy...etc. Cohort study is also known as prospective study or incidence study .Because the data collected at different points in time, cohort study is longitudinal.

Design of a cohort study:



3-Ecological studies (correlational study):

In this study, the units of analysis are populations or groups of people rather than individuals. For example, in one country a relationship was demonstrated between average sales of an anti-asthma drug and the occurrence of an unusually high number of asthma deaths. Such relationships may be studied by comparing populations in different countries at the same time or the same population in one country at different times.

2-Experimental studies (intervention studies):

After a disease has been described and analyzed, various modes of intervening the disease are tried. So that the main purpose of experimental epidemiology is to: a-provide scientific proof of etiological factor by using an intervention.

b-Provide a method of measuring the effectiveness and efficacy of health services for the prevention ,control and treatment of disease.

Intervention

A diagnostic test or procedure, prescribed therapy, or other action intended to detect, prevent or treat a health condition. The effects of an intervention or experimentation are measured by comparing the outcome (disease) in the experimental group with that in a control group.

There are 3 types of experimental studies:

1-Randomized controlled trials (randomized clinical trial):-

A clinical study in which participants is randomly (i.e., by chance) assigned to either an experimental group or control group. The experimental group receives the new intervention and the control group receives a placebo or standard intervention. These groups followed for the outcomes of interest which could be the development of a new disease or recovery from established disease. These studies are one of the best methods to test preventive and therapeutic measures.

Randomization:

It is a statistical procedure by which the participants are allocated into groups usually study and control groups, to receive or not to receive an experimental preventive or therapeutic measure, procedure or intervention.

Blinding:

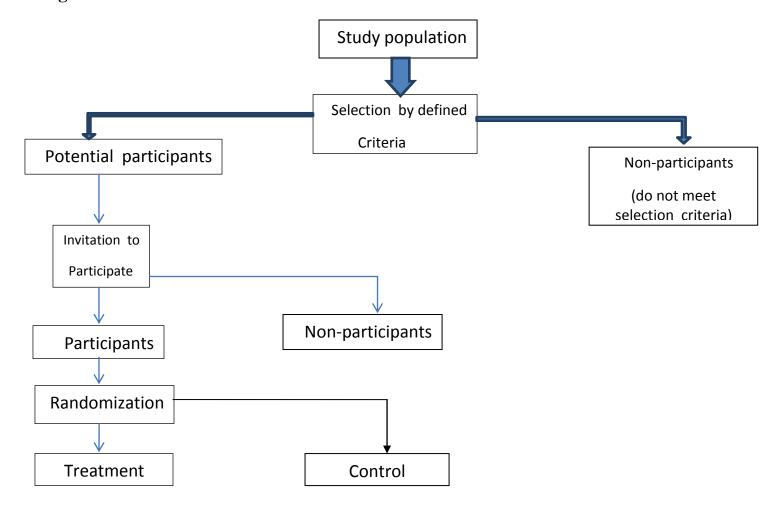
Is a procedure done to reduce the bias which may occur due to errors from assessment of the outcome. The subjects need to participate without knowing which type of intervention is being done on them.

Blinding is of three types

- 1-**Single blind trial**: The trial is planned in such a way that the participant is not aware whether he belongs to the study group or control group.
- 2-**Double blind trial**: The trial is so planned that neither the investigator nor the participant is aware of the group allocation and the treatment received.

3-**Triple blind trial**: The trial is planned in such a way that the participant ,the investigator and the person analyzing the data are all blind.

Design of randomized controlled trial:



2-Field trials:

These studies involve people who are disease-free but presumed to be at risk, data collection takes place in the field .Since the subjects are disease-free and the purpose is to prevent the occurrence of disease that may occur with relatively low frequency, field trials are often huge undertakings involving major logistic and financial considerations. Example: using preventive measures like vaccination against disease or specific risk factors are averted in groups of population and the reduction of disease incidence observed, e.g. sugars and caries.

3-Community trials:

In this form of experiment the treatment groups are communities rather than individuals. A limitation of such studies is that only a small number of communities can be included and random allocation of communities is not practicable. In this type of study the whole community is taken as the study group, such studies are the only way in which a general intervention like fluoridation has to be tried out for reducing dental caries. Communities in the neighborhood is taken as the control group for comparison.