

بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ

In the name of **ALLAH**
the most Beneficent and the most merciful

بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ
HALLA 2002





EPIDEMIOLOGICAL STUDIES

EPIDEMIOLOGICAL STUDIES

A study design is a specific plan or protocol for conducting the study, which allows the investigator to translate the **conceptual** hypothesis into an **operational** one.

Direction of Study

Backward

Forward



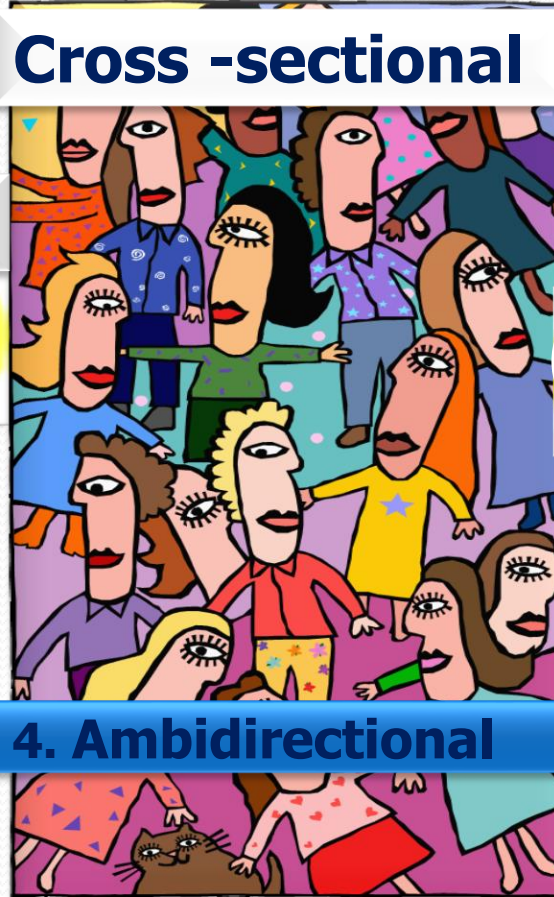
Cross-sectional

Retrospective

Prospective



4. Ambidirectional



EPIDEMIOLOGICAL STUDIES

CLASSIFICATION

- Various ways
- BUT, two major classes
 - Non-Interventional
 - Interventional

Non-Intervention studies

- Researcher **do not manipulate** situations/objects
- Just describes or analyses situations/objects

Intervention studies

- Researcher **manipulates** situations/objects then describes or analyses the outcome

Decision Tree

Intervention Done

No

Observational Study

Comparison Group

No

Descriptive Study

Yes

Analytic Study

Direction of Study

E → O

Cohort Study

E = O

Cross-Sectional Study

E ← O

Case-Control Study

Yes

Experimental Study

Randomization

No

NRCT Study

Yes

RCT Study

EPIDEMIOLOGICAL STUDIES

- Epidemiological studies can be classified as observational studies and experimental studies with further subdivisions:
- 1. Observational studies
 - a. Descriptive studies b. Analytical studies
 - (i) Ecological or Correlational, with populations as unit of study
 - (ii) Cross-sectional or Prevalence, with individuals as unit of study
 - (iii) Case-control or Case-reference ,with individuals as unit of study
 - (iv) Cohort or Follow-up, with individuals as unit of study

EPIDEMIOLOGICAL STUDIES

- 2. Experimental studies/ Intervention studies
 - a. Randomized controlled trials or Clinical trials with patients as unit of study
 - b. Field trials with healthy people as unit of study
 - c. Community trials or Community intervention studies with communities as unit of study

DESCRIPTIVE EPIDEMIOLOGY

- The best study of mankind is man. This statement emphasizes the importance of making the best use of observations on individuals or populations exposed to suspected factors of disease.

DESCRIPTIVE EPIDEMIOLOGY

- Descriptive studies are usually the first phase of an epidemiological investigation. These studies are concerned with observing the distribution of disease or health-related characteristics in human populations and identifying the characteristics with which the disease in question seems to be associated

DESCRIPTIVE EPIDEMIOLOGY

- Such studies basically ask the questions.
- **a.** When is the disease occurring ?--time distribution
- **b.** Where is it occurring?--- - place distribution
- **c.** Who is getting the disease? - person distribution

DESCRIPTIVE EPIDEMIOLOGY

- Procedures in descriptive studies
- 1. Defining the population to be studied
- 2. Defining the disease under study
- 3. Describing the disease by a. time b. place c. person
- 4. Measurement of disease
- 5. Comparing with known indices
- 6. Formulation of an aetiological hypothesis

DESCRIPTIVE EPIDEMIOLOGY

- 1. *Defining the population*
- Descriptive studies are investigations of populations, not individuals. The first step is, therefore, to define the "population base" not only in terms of the total number, but also its composition in terms of age, sex, occupation, cultural characters etc.

DESCRIPTIVE EPIDEMIOLOGY

- The "defined population" can be the whole population in a geographic area, or more often a representative sample taken from it. The defined population can also be a specially selected group such as age and sex groups, occupational groups, hospital patients, school children, small communities as well as wider groupings

DESCRIPTIVE EPIDEMIOLOGY

- The community chosen should be stable, without migration into or out of the area. It should be clear who does and who does not belong to the population, as for example, visitors and relations.

DESCRIPTIVE EPIDEMIOLOGY

- The concept of 'defined population' (or population at risk) is crucial in epidemiological studies. It provides the denominator for calculating rates which are essential to measure the frequency of disease and study its distribution and determinants. Epidemiologists therefore have been labelled as men in search of a denominator

DESCRIPTIVE EPIDEMIOLOGY

- 2. Defining the disease under study
- Once the population to be studied is defined or specified, one must then define the disease or condition being investigated. Here the needs of the clinician and epidemiologist may diverge. The clinician may not need a precise definition of disease (e.g., *migraine*) for immediate patient care. If the diagnosis is wrong, he can revise it subsequently.

DESCRIPTIVE EPIDEMIOLOGY

- But the epidemiologist, whose main concern is to obtain an accurate estimate of disease in a population, needs a definition that is both *precise and valid* to enable him to identify those who have the disease from those who do not. The diagnostic methods for use in epidemiological studies must be acceptable to the population to be studied, and applicable to their use in large populations.

DESCRIPTIVE EPIDEMIOLOGY

- 3. Describing the disease
- The primary objective of descriptive epidemiology is to describe the occurrence and distribution of disease by **time, place and person**, and identifying those characteristics associated with presence or absence of disease in individuals. This involves systematic collection and analysis of data.

DESCRIPTIVE EPIDEMIOLOGY

- TIME DISTRIBUTION

- The pattern of disease may be described by the time of its occurrence, i.e., by week, month, year, the day of the week, hour of onset, etc. It raises questions whether the disease is seasonal in occurrence; whether it shows periodic increase or decrease; or whether it follows a consistent time trend. Such studies may yield important clues about the source or aetiology of the disease, thereby suggesting potential preventive measures.

DESCRIPTIVE EPIDEMIOLOGY

- Epidemiologists have identified three kinds of time trends or fluctuations in disease occurrence.
- I. Short-term fluctuations
- II Periodic fluctuations, and
- III. Long-term or secular trends

DESCRIPTIVE EPIDEMIOLOGY

- *I. Short-term fluctuations*
- The best known short-term fluctuation in the occurrence of a disease is an epidemic. According to modern concepts an epidemic is defined as "the occurrence in a community or region of cases of an illness or other health-related events clearly in excess of normal expectancy".

DESCRIPTIVE EPIDEMIOLOGY

- **Types of epidemics**
- **A.** Common-source epidemics (a) Single exposure or "point-source" epidemics. (b) Continuous or multiple exposure epidemics
- **B.** Propagated epidemics (a) Person-to-person (b) Arthropod vector (c) Animal reservoir
- **C.** Slow (modern) epidemics.

DESCRIPTIVE EPIDEMIOLOGY

- A graph of the time distribution of epidemic cases is called the "**epidemic curve**". The epidemic curve may suggest :
 - (1) a time relationship with exposure to a suspected source,
 - (2) a cyclical or seasonal pattern suggestive of a particular infection, and common source or propagated spread of the disease.

DESCRIPTIVE EPIDEMIOLOGY

- **A. Common-source epidemics**
- (a) Common-source, single exposure epidemics
- These are also known as "point-source" epidemics. The exposure to the disease agent is brief and essentially simultaneous, the resultant cases all develop within one incubation period of the disease (e.g., an epidemic of food poisoning).

DESCRIPTIVE EPIDEMIOLOGY

- The main features of a "point-source" epidemic are :
 - (i) the epidemic curve rises and falls rapidly, with no secondary waves
 - (ii) the epidemic tends to be explosive, there is clustering of cases within a narrow interval of time, and
 - (iii) more importantly, all the cases develop within one incubation period of disease.

DESCRIPTIVE EPIDEMIOLOGY

- (b) Common-source, continuous or repeated exposure
- Sometimes the exposure from the same source may be prolonged - continuous, repeated or intermittent - not necessarily at the same time or place. A prostitute may be a common source in a gonorrhoea outbreak, but since she will infect her clients over a period of time there may be no explosive rise in the number of cases.

DESCRIPTIVE EPIDEMIOLOGY

- A well of contaminated water, or a nationally distributed brand of vaccine (e.g. polio vaccine), or food, could result in similar outbreaks. In these instances, the resulting epidemics tend to be more extended or irregular.

DESCRIPTIVE EPIDEMIOLOGY

- *B. Propagated epidemics*
- A propagated epidemic is most often of infectious origin and results from person-to-person transmission of an infectious agent (e.g., epidemics of hepatitis A and polio). The epidemic usually shows a gradual rise and tails off over a much longer period of time. Transmission continues until the number of susceptibles is depleted or susceptible individuals are no longer exposed to infected persons or intermediary vectors.

DESCRIPTIVE EPIDEMIOLOGY

- *II. Periodic fluctuations*
- (i) **Seasonal trend** : Seasonal variation is a well-known characteristic of many communicable diseases, e.g., measles, varicella, cerebro-spinal meningitis, upper respiratory infections, malaria, etc.
- For example, measles is usually at its height in early spring and so is varicella. Upper respiratory infections frequently show a seasonal rise during winter months. Bacterial gastrointestinal infections are prominent in summer months because of warm weather and rapid multiplication of flies.

DESCRIPTIVE EPIDEMIOLOGY

- The seasonal variations of disease occurrence may be related to environmental conditions (e.g., temperature, humidity, rainfall, overcrowding, life cycle of vectors, etc.) which directly or indirectly favour disease transmission.
- Noninfectious diseases and conditions may sometimes exhibit seasonal variation, e.g., *sunstroke, hay fever, snakebite.*

DESCRIPTIVE EPIDEMIOLOGY

- (ii) **Cyclic trend** : Some diseases occur in cycles spread over short periods of time which may be days, weeks, months or years. For example, **measles** in the pre vaccination era appeared in cycles with major peaks **every 2-3 years** and **rubella every 6-9 years**. This was due to naturally occurring variations in herd immunity

DESCRIPTIVE EPIDEMIOLOGY

- **Influenza pandemics** are known to occur at intervals of **7-10 years**, due to antigenic variations.
- Non-infectious conditions may also show periodic fluctuations, e.g., automobile accidents in US are more frequent on weekends, especially Saturdays.

DESCRIPTIVE EPIDEMIOLOGY

- *III. Long-term or secular trends*
- The term "secular trend" implies changes in the occurrence of disease (i.e., a progressive increase or decrease) over a long period of time, generally several years or decades.
- Examples include **coronary heart disease, lung cancer and diabetes** which have shown a consistent upward trend in the developed countries during the past 50 years or so, followed by a decline of such diseases as **tuberculosis, typhoid fever, diphtheria and polio.**

PLACE DISTRIBUTION

- Studies of the geography of disease (or geographical pathology) is one of the important dimensions of descriptive epidemiology.
- The world is not a uniform unit. **Cultures, standard of living and external environments vary greatly.** The use of migrant studies is one way of distinguishing genetic and environmental factors.

PLACE DISTRIBUTION

- Geographic patterns provide an important source of clues about the causes of the disease.
- variations may be classified as :
 - a. International variations
 - b. National variations
 - c. Rural-urban variations
 - d. Local distributions

PLACE DISTRIBUTION

- **International variations**
- Descriptive studies by place have shown that the pattern of disease is not the same everywhere. For example, we know that **cancer** exists all over the world. There is however, a marked difference between the incidence of each cancer in different parts of the world.

PLACE DISTRIBUTION

- Thus cancer of the **stomach** is very common in **Japan**, but unusual in US. Cancers of the **oral cavity and uterine cervix** are exceedingly common in **India** as compared to industrialized countries. An international study of **breast cancer** showed that rates differ widely from country to country with the lowest prevalence in **Japan** and the highest in the **western countries**.

PLACE DISTRIBUTION

- Similarly, there are marked international differences in the occurrence of **cardiovascular diseases**. These variations have stimulated epidemiologists to search for **cause-effect relationships** between the environmental factors and disease.

PLACE DISTRIBUTION

- National variations

- It is obvious that variations in disease occurrence must also exist within countries. For example the distribution of endemic goitre, fluorosis, leprosy, malaria, nutritional deficiency diseases have all shown variations in their distribution in Pakistan, with some parts of the country more affected and others less affected or not affected at all. Such situations exist in every country.

PLACE DISTRIBUTION

- Rural-urban variations
- Rural/urban variations in disease distribution are well known. Chronic bronchitis, accidents, lung cancer, cardiovascular diseases, mental illness and drug dependence are usually more frequent in urban than in rural areas.

PLACE DISTRIBUTION

- On the other hand, **skin and zoonotic diseases and soil-transmitted helminths** may be more frequent in rural areas than in urban areas.
- The epidemiologist seeks to define groups which are at higher risk for particular diseases, and provides guidelines to the health administrator for their prevention and control.

PLACE DISTRIBUTION

- Inner and outer city variations in disease frequency are well known. These variations are best studied with the aid of '**spot maps**' or '**shaded maps**'. These maps show at a glance areas of high or low frequency, the boundaries and patterns of disease distribution.

PLACE DISTRIBUTION

- For example if the map shows "clustering" of cases, it may suggest a common source of infection or a common risk factor shared by all the cases. It was by such a study (spot map of fatal cases), John Snow of England in his classic investigation of cholera epidemic in 1854 in the Golden Square district of London was able to focus attention on the common water pump in Broad street as the source of infection

PLACE DISTRIBUTION

- **Migration studies**
- Large scale migration of human populations from one country to another provides a unique opportunity to evaluate the role of the possible genetic and environmental factors in the occurrence of disease in a population.

PLACE DISTRIBUTION

- Supposing there are marked geographic differences in the occurrence of a disease in two areas, area "A" and area "B"
- Let us assume that the environments in these two places are very different. The question arises whether the environmental differences in the two areas account for the variations in the occurrence of the disease in question.

PLACE DISTRIBUTION

- Ideally samples of population in area “A” should be sent to area "B", and vice versa to study change in incidence of disease. In human populations this is hardly possible, so we restrict our study to observation of changes in disease frequency among migrants.

PLACE DISTRIBUTION

- Migrant studies can be carried out in two ways :
- (a) comparison of disease and death rates for **migrants** with those of their kin who have **stayed at home**. This permits study of genetically similar groups but living under different environmental conditions or exposures.

PLACE DISTRIBUTION

- If the disease and death rates in migrants are **similar to country of adoption** over a period of time, the likely explanation would be **change in the environment**. A special case is the use of twins who have been exposed to different environments of migration.

PLACE DISTRIBUTION

- (b) comparison of migrants with local population of the host country provides information on genetically different groups living in a similar environment. If the migration rates of disease and death are **similar** to the **country of origin**, the likely explanation would be the **genetic factors**.

PLACE DISTRIBUTION

- Migrant studies have shown that men of Japanese ancestry living in USA experience a higher rate of **coronary heart** disease than do the Japanese in Japan .
- Taking another example, Japan has a higher rate for **stomach cancer** and a lower rate for **colon cancer** than the United States has. However, third-generation descendants of Japanese immigrants to USA have rates of stomach and colon cancer like those of the total **US population**.

PLACE DISTRIBUTION

- These studies suggest that as the Japanese were probably adopting the American way of life, their susceptibility to coronary heart disease, gastric and colonic cancer was moving in the direction of that found in the Americans.

PERSON DISTRIBUTION

- In descriptive studies, the disease is further characterized by defining the persons who develop the disease by age, sex, occupation, marital status, habits, social class and other host factors.

PERSON DISTRIBUTION

- (a) **Age** : Age is strongly related to disease than any other single host factor. Certain diseases are more frequent in certain age groups than in others, e.g., **measles in childhood, cancer in middle age and atherosclerosis in old age.**

PERSON DISTRIBUTION

- **Bimodality** : Sometimes there may be two separate peaks instead of one in the age incidence curve of a disease as in the case of **Hodgkin's disease, leukaemia, and female breast cancer**. This phenomenon is known as bimodality.
- The curve is bimodal with an initial peak between the ages **15 and 35** years, and a later peak starting at age **50**.

PERSON DISTRIBUTION

- **(b) Sex** : Sex is another host characteristic which is often studied in relation to disease, using such indices as sex-ratio, sex-specific morbidity and mortality rates. It has been found that certain chronic diseases such as **diabetes, hyperthyroidism and obesity** are strikingly more common in women than in men, and diseases such as **lung cancer and coronary heart disease** are less frequent in women.

PERSON DISTRIBUTION

- (c) **Ethnicity:** Differences in disease occurrence have been noted between population subgroups of different racial and ethnic origin. These include **tuberculosis, essential hypertension, coronary heart disease, cancer, and sickle cell anaemia.** These differences, whether they are related to genetic or environmental factors, have been a stimulus to further studies.

PERSON DISTRIBUTION

- **(d) Marital status** : In countries where studies on mortality in relation to marital status have been conducted, it was found that **mortality rates were always lower for married males and females than for the unmarried, of the same age and sex.**

PERSON DISTRIBUTION

- Married persons are generally more secure and protected and they usually lead a **more sober life** than those who are unmarried. All these factors are thought to contribute to lower mortality rates among married persons.

PERSON DISTRIBUTION

- Marital status can be a risk factor for some diseases and conditions. The observation that cancer cervix is rare in nuns led to the hypothesis regarding marital status and cancer cervix. Further studies led to the suggestion that cancer cervix may be associated with multiple sexual contacts. This in turn raised the possibility of a possible infectious agent transmitted venereally

PERSON DISTRIBUTION

- (e) **Occupation** : It is now well recognized that man's occupation from which he earns his livelihood has an important bearing on his health status. Occupation may alter the habit pattern of employees e.g., **sleep, alcohol, smoking, drug addiction, night shifts etc.**

PERSON DISTRIBUTION

- It is obvious that persons working in particular occupations are exposed to particular types of risks. For instance, while workers in **coal mines** are more likely to suffer from silicosis, those in **sedentary occupations** face the risk of **heart disease**.

PERSON DISTRIBUTION

- (f) **Social class** : Epidemiological studies have shown that health and diseases are not equally distributed in social classes. Individuals in the **upper social classes** have a longer life expectancy and better health and **nutritional status** than those in the lower social classes

PERSON DISTRIBUTION

- Certain diseases (e.g., **coronary heart disease, hypertension, diabetes**) have shown a higher prevalence in upper classes than in the lower classes. Social class differences have also been observed in **mental illness** and utilization of medical and health care services.

PERSON DISTRIBUTION

- (g) **Behaviour** : Human behaviour is increasingly looked upon as a risk factor in modern-day diseases such as **coronary heart disease, cancer, obesity and accidents**.
- The behavioural factors which have attracted the greatest attention are **cigarette smoking, sedentary life, over-eating and drug abuse**.

PERSON DISTRIBUTION

- **(h) Stress** : Stress has been shown to affect a variety of variables related to patients response, e.g., susceptibility to disease, exacerbation of symptoms, compliance with medical regimen, etc.

PERSON DISTRIBUTION

- (i) Migration : diseases like leprosy, filaria and malaria are considered to be rural problems. However, because of the movement of people from rural to urban areas these diseases have created a serious problem in urban areas also. Human movement may be classified (i) as short-term, long-term, and permanent (ii) according to age, sex, education, occupation, (iii) internal or external (iv) urban versus rural, etc.

4. Measurement of disease

- It is mandatory to have a clear picture of the amount of disease ("disease load") in the population. This information should be available in terms of mortality, morbidity, disability and so on, and should preferably be available for different subgroups of the population.

4. Measurement of disease

- Measurement of mortality is straightforward. Morbidity has two aspects - incidence and prevalence . **Incidence** can be obtained from "longitudinal" studies, and **prevalence** from "cross-sectional" studies.

4. Measurement of disease

- **Cross-sectional studies**

- Cross-sectional study is the simplest form of an observational study. It is based on a single examination of a cross-section of population at one point in time - the results of which can be projected on the whole population provided the sampling has been done correctly. Cross-sectional study is also known as "**prevalence study**".

4. Measurement of disease

- **Longitudinal studies**
- There is an increasing emphasis on the value of longitudinal studies in which observations are repeated in the same population over a prolonged period of time by means of follow-up examinations. **Cross-sectional studies** have been likened to a **photograph**, and **longitudinal studies** to a **cine film**

4. Measurement of disease

- Longitudinal studies are useful
- (i) to study the natural history of disease and its future outcome
- (ii) for identifying risk factors of disease, and
- (iii) for finding out incidence rate or rate of occurrence of new cases of disease in the community.

4. Measurement of disease

- Longitudinal studies provide **valuable information** which the cross-sectional studies may not provide, but longitudinal studies are **difficult to organize** and **more time-consuming** than cross-sectional studies.

5. Comparing with known indices

- The essence of epidemiology is to make **comparisons** and **ask questions**. By making comparisons between different populations, and subgroups of the same population, it is possible to arrive at clues to disease aetiology. We can also identify or define groups which are at increased risk for certain diseases.

6. Formulation of a hypothesis

- By studying the **distribution of disease**, and utilizing the techniques of descriptive epidemiology, it is often possible to **formulate hypotheses** relating to disease aetiology. A hypothesis is a **supposition**, arrived at from observation or reflection. It can be accepted or rejected, using the techniques of analytical epidemiology.

6. Formulation of a hypothesis

- An epidemiological hypothesis should specify the following
 - **a.** the population the characteristics of the persons to whom the hypothesis applies
 - **b.** the specific cause being considered
 - **c.** the expected outcome - the disease

6. Formulation of a hypothesis

- **d.** the dose-response relationship - the amount of the cause needed to lead to a stated incidence of the effect
- **e.** the time-response relationship the time period that will elapse between exposure to the cause and observation of the effect.

6. Formulation of a hypothesis

- For example :
- "Cigarette smoking causes lung cancer"
- is an incomplete hypothesis.
- An improved formulation
- "The smoking of 30-40 cigarettes per day causes lung cancer in 10 per cent of smokers after 20 years of exposure"

Uses of descriptive epidemiology

- (a) provide data regarding the magnitude of the disease load and types of disease problems in the community in terms of morbidity and mortality rates and ratios.
- (b) provide clues to disease aetiology, and help in the formulation of an aetiological hypothesis. That is, the existence of a possible causal association between a factor and a disease is usually recognized in descriptive studies.

Uses of descriptive epidemiology

- (c) provide background data for planning, organizing and evaluating preventive and curative services, and
- (d) they contribute to research by describing variations in disease occurrence by time, place and person.

THANK
YOU

THAT IS LIFE

