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2nd Edition

A Comprehensive Textbook of Community Health Nursing

As per Revised Nursing Syllabus

Bijayalaskhmi Dash

JAYPEE

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CHAPTER 3

Epidemiology

JAYPEE BROTHERS

CONCEPT OF EPIDEMIOLOGY

Epidemiology is the basic science of preventive and social medicine. The science of epidemiology deals with the study of health-related states and events occurring in a population. Epidemiology helps in understanding the health concepts, natural history of disease and disease causation. It also helps in planning, implementing and evaluating effective and efficient healthcare services. Epidemiology is a quantitative basic science built on a working knowledge of probability, statistics, and sound research methods, a method of causal reasoning based on developing and testing hypotheses pertaining to occurrence and prevention of morbidity and mortality; and a tool for public health action to promote and protect the public's health based on science, causal reasoning, and a dose of practical common sense.

The term epidemiology is derived from the term epidemic. The literal meaning of the term is study among people Epi = among, demos = people, logus = study.

Definitions

- According to Parkin, 1873 the epidemiology is that branch of medical science which deals with epidemics
- According to Frost, 1927 Epidemiology is the science of mass phenomena of infectious diseases
- Greenwood, 1934 stated that Epidemiology is the study of disease, any disease, as a mass phenomenon
- Epidemiology is the study of distribution and determinants of disease frequency in man. **—MacMohan, 1960**
- Clark, 1965 described the Epidemiology as the study of various factors and conditions that determine the occurrence and distribution of health disease defect, disability and death among groups or individuals
- Epidemiology is concerned with the study of processes which determine or influence the physical, mental and social health of people. **—Cassel, 1965**
- Epidemiology is the study of the distribution of a disease or a physiological condition in human populations and of factors that influence this distribution. **—Lelien Field**

The most acceptable definition of Epidemiology is 'Epidemiology is the study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to the control of health problems.' **—M last,1988**

This definition of epidemiology includes several terms which reflect some of the important principles of the discipline. The description of these terms are given below.

Study

Epidemiology is a scientific discipline, sometimes called 'the basic science of public health.' It has, at its foundation, sound methods of scientific inquiry. It is a highly quantitative discipline based on principles of statistics and research methodologies.

Distribution

Epidemiologists study the distribution of frequencies and patterns of health events within groups in a population. Frequency includes not only the number of such events in a population, but also the rate or risk of disease in the population. The rate (number of events divided by size of the population) is critical to epidemiologists because it allows valid comparisons across different populations. Pattern refers to the occurrence of health-related events by time, place, and personal characteristics.

- Time characteristics include annual occurrence, seasonal occurrence, and daily or even hourly occurrence during an epidemic
- Place characteristics include geographic variation, urban-rural differences, and location of work sites or schools
- Personal characteristics include demographic factors such as age, race, sex, marital status, and socioeconomic status, as well as behaviors and environmental exposures.

Determinants

Epidemiology is also used to search for causes and other factors that influence the occurrence of health-related events. Epidemiology will search for the factors which are responsible for disease may agent, host and environmental factors. Analytic epidemiology attempts to provide the Why and How of such events by comparing groups with different rates of disease occurrence and with differences in demographic characteristics, genetic or immunologic

make-up, behaviors, environmental exposures, and other so-called potential risk factors. Under ideal circumstances, epidemiologic findings provide sufficient evidence to direct swift and effective public health control and prevention measures.

Health-related States or Events

Originally, epidemiology was concerned with epidemics of communicable diseases. Then epidemiology was extended to endemic communicable diseases and non-communicable infectious diseases. Now epidemiology deals with any health-related states or events which include any type of accidents, chronic diseases, injuries, birth defects, maternal-child health, occupational health, and environmental health. Now, even behaviors related to health and well-being (amount of exercise, seat-belt use, etc.) are recognized as valid subjects for applying epidemiologic methods. Here, we use the term 'disease' to refer to the range of health-related states or events.

Specified Populations

Specified populations include population in a specific community. Although epidemiologists and physicians in clinical practice are both concerned with disease and the control of disease, they differ greatly in how they view 'the patient.' Clinicians are concerned with the health of an individual; epidemiologists are concerned with the collective health of the people in a community or other area. When faced with a patient with diarrheal disease, for example, the clinician and the epidemiologist have different responsibilities. Although both are interested in establishing the correct diagnosis, the clinician usually focuses on treating and caring for the individual. The epidemiologist focuses on the exposure the number of other persons who may have been similarly exposed, the potential for further spread in the community, and interventions to prevent additional cases or recurrences.

Application

The different health program for control of communicable and noncommunicable diseases are initiated on applying the result of epidemiological investigation. Epidemiology provides data for directing public health action. Using epidemiologic data is an art as well as a science. To treat patient, a clinician must call upon experience and creativity as well as scientific knowledge. Similarly, an epidemiologist uses the scientific methods of descriptive and analytic epidemiology in 'diagnosing' the health of a community, but also must call upon experience and creativity when planning how to control and prevent disease in the community.

Epidemiologic Process

Epidemiological process tells the answer of five questions thats are who was affected? Where were they affected? When were they affected? How they affected and why they affected? Who refers to personal characteristics, i.e., age, sex, race/ethnicity, socioeconomic status and behaviors where refers to place, geographic distribution clustering, uniform, scattered home, work, school and hospital when refers to time, i.e., onset of symptoms, incubation period, infectious period, seasonality, epidemic, interval and long-term trends.

According to different epidemiologist, epidemiology is:

- An inductive method applied to a large group
- A research method of public health
- The science of public health
- The study of statistics of disease in population
- The quantitative science. The measured quantities and descriptive terms used to describe groups
- The measurement of risk of diseases in community
- The study of epidemics of hard to large group
- A method of diagnosing the conditions of the people
- The study of health of population in relation to their environment and ways of living.

Modern Epidemiology Deals with

- Measurement of occurrence of health-related states and events, i.e., health needs, health demands, impact of health services and measurement of frequency of disease, disability or death. The measurement are done in the form of rates, ratios and proportion, i.e., incidence rate, prevalence rate, male-female ratio percentage of children with malnutrition.
- Distribution of disease pattern in a community by time, place and person
- Testing of etiological hypothesis derived from descriptive study of diseases and health-related events
- Planning of healthcare services based on the studies, implementation and evaluation of healthcare services.

Aims of Epidemiology

The basic purposes of epidemiology are:

- To prevent control and eradicate health-related problems
- To minimize the impact of these problems
- To promote health and quality of life of people at large.

Objectives of Epidemiology

1. To describe the distribution and magnitude of health and disease problems in the population
2. To identify the etiological factors—risk factors in the population
3. To provide the data essential to planning, implementation and evaluation of services for prevention, control and treatment of disease and to setting up of priorities for these services.

Scope of Epidemiology

The scope of epidemiology is ever increasing. It is destined grow to further to meet new emerging challenges to health and survival of man on this planet. Now it stresses the concept of excessive prevalence of disease as its basic implication. Epidemiologists are now concerned not only

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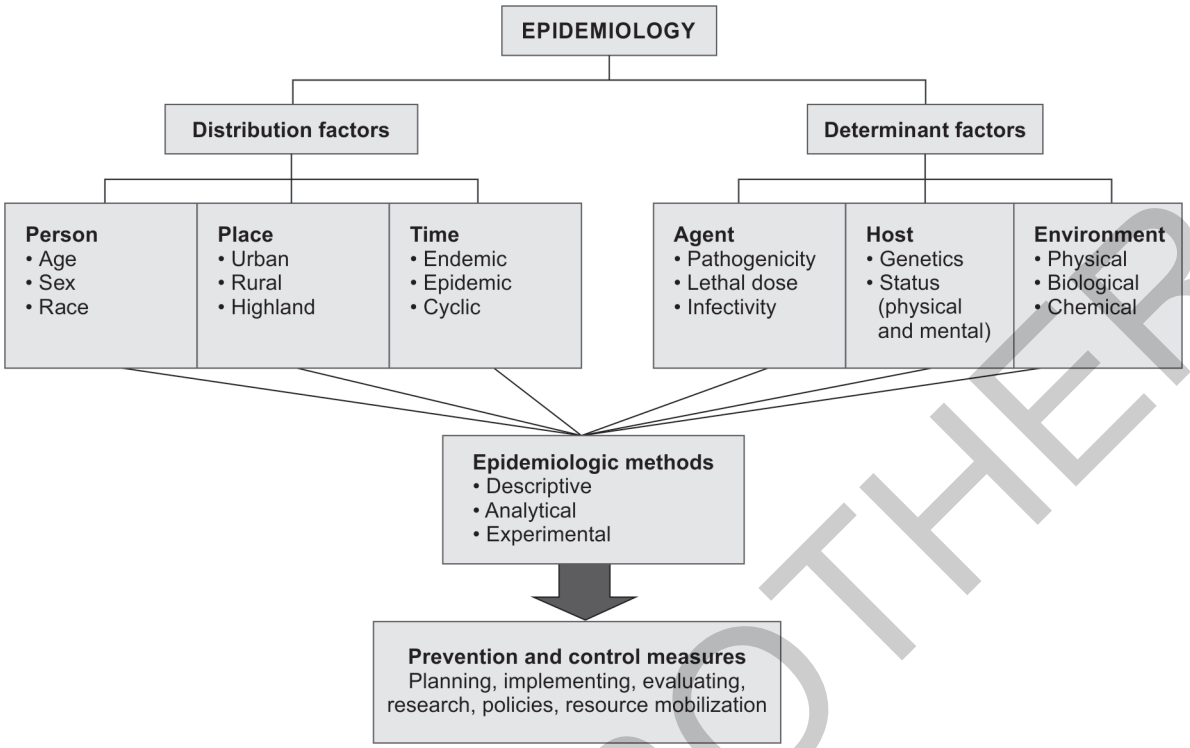

Fig. 3.1: Models of epidemiology.

with infectious diseases but also with noninfectious diseases, i.e., coronary heart disease, diabetes, accidents, injuries, cancer, and mental illness.

Thus, modern epidemiology has taken within its scope all diseases whether acute or chronic, physical or mental, communicable or noncommunicable and health-related states and events occurring in human population.

We have also seen that epidemiology is the study of disease/conditions distribution and determinants. As a science, it utilises rational study methods in identifying the distribution patterns and determinants of diseases. From the studies, recommendations are generated on how to:

- Plan for disease prevention and control
- Predict the disease patterns for effective prevention and control
- Mobilize resources for effective prevention and control
- Evaluate programs for disease prevention and control
- Develop evidence based and practical policies for effective disease prevention and control
- Develop a data base for further studies in epidemiology of diseases and conditions **(Fig. 3.1)**. Epidemiological models of causation of disease is already described in Chapter 1.

HISTORICAL BACKGROUND AND TRENDS OF EPIDEMIOLOGY

Although epidemiologic thinking has been traced from Hippocrates (Circa 400 BC) through Graunt (1662), Farr, Snow (both mid-1800's), and others, the discipline did not blossom until the end of the Second World War. Hippocrates (Circa 400 BC) attempted to explain disease occurrence from a rational instead of a supernatural viewpoint. In his essay entitled 'On Airs, Waters, and Places,' Hippocrates suggested that environmental and host factors such as behaviors might influence the development of disease. Another early contributor to epidemiology was John Graunt, a London haberdasher who published his landmark analysis of mortality data in 1662. He was the first to quantify patterns of birth, death, and disease occurrence, noting male-female disparities, high infant mortality, urban rural differences, and seasonal variations. No one built upon Grant's work until the mid-1800's.

When William Farr began to systematically collect and analyze Britain's mortality statistics, Farr considered the father of modern vital statistics and surveillance, developed many of the basic practices used today in vital statistics and disease classification. He extended the epidemiologic analysis of morbidity and mortality data, looking at the effects of marital status, occupation, and altitude. He also developed many epidemiologic concepts and techniques still in use today. Epidemiology is derived from the word epidemic. (epi – among, demos – people, logos – study). The foundation of morden epidemiology was laid in a 19th century when a few classic studies made a major contribution to the saving of life. In 1850, under the presidency of Earl of Shaft Esbury, an epidemiological society was made. In early 1920 Winslow and Sedgwick both lectured on epidemiology in United States. Although the subject was not given departmental status in 1927. WH Frost become the first professor of epidemiology in US. Later Major Greenwood become first professor of epidemiology and medical studies in the University of London. Epidemiology has grown rapidly during the first

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three decades. It has now become firmly established in medical education.

On analysis disease condition, there had been considerable reduction in the morbidity and mortality from these diseases, as a result of epidemiological studies and improved methods of diagnosis prevention and control. But still due to poor socioeconomic conditions, ignorance poor health practices and inadequate resources the epidemic is continued. While many communicable diseases continue to be a serious problems of community health, many new problems have emerged in the 20th century. These problems include cardiovascular diseases, mental health problems, cancer, accidents, immunodeficiency diseases and many other problems related to lifestyle, environment, advance technology and stress. These noncommunicable diseases are due to changing environment or ecosystem. Currently the focus of epidemiologists are not only limited to the infectious diseases but also on these new emergent problems. It is expected to have many more new problems and hazards related to computer technology, electric appliances, space travel and increased leisure time and sedentary life, etc. The review of historical traced back to Hippocrates (460-547 BC) who tried to explain the association of lifestyle and environmental factors with the occurrence of diseases. However, the foundation of modern epidemiology was laid down on late 20th century when infectious and communicable diseases like cholera, typhoid, plague, etc., were most prevalent in the world in the form of epidemic and pandemics. Other communicable diseases which were the major concerns of epidemiologists and public health personnel include small pox, TB poliomyelitis, measles, STDs. Epidemiology became a distinct branch of medical science and it flourished as a result of study and control of these communicable infectious diseases. Thus during late 19th century and early 20th century, the primary focus of epidemiologists was to study the prevalence, prevention and control of various infectious and communicable diseases.

Significant Mile Stones in the History of Epidemiology

- **1662 (John Graun):** Used bills of mortality to study patterns of death in various populations in England. Published early form of life table analysis
- **1747 (James Lind):** Study of scurvy using observation and comparison of response to various dietary treatments. Early precursor of clinical trial
- **1760 (Daniel Bernoulli):** Used life table technique to demonstrate that small pox inoculation conferred life long immunity
- **1775 (Percival Pott):** First cancer epidemiologist noted high proportion of patients presenting with cancer of scrotum were chimney sweep
- **1798 (Edward Jenner):** Demonstrated effectiveness of small pox vaccination
- **1798 (Marrie Hospital service):** Fore runner of US Public health services (1912)
- **1836 (Pierre Charles—Alexander Louis):** Comparative observational studies to demonstrate ineffectiveness of bloodletting emphasized the importance of statistical method
- **1840 (William Farr):** Developed for runner of middle vital records system in regular general's office
- **1850 (Lemuel Shattuck):** Report on sanitation and public health in Massachusetts
- **1850 (John Snow):** Epidemiologic research on transmission of cholera
- **1870–1880:** Discovery of casual agents for anthrax, TB and cholera
- **1887 (Joseph Kinyion):** Founded laboratory of hygiene, fore runner of the national institute of health
- **1921 (Wade Hampton Frost):** Founded first US academic program in epidemiology at Johns Hipkins

In fact epidemiology includes the study of all those conditions which affect the health of the people.

METHODS OF EPIDEMIOLOGICAL INVESTIGATION

The epidemiologist and community health workers are interested in the study of health status of the population by which they identifies morbidity and mortality patterns, determines the factors affecting health and disease and utilizes this information in planning to provide need-based health care. The epidemiological investigation requires:

- Systematic collection of data
- Analysis of data
- Description of health needs and problems
- Identification of factors associated with problems and stating the hypothesis which are further explored and tested.

The epidemiologist try to relate the cases to define population and search for the causes of disease and mode of transmission affects the prevention and control and eradication. The methods of epidemiological investigations are:

- Observational method
- Experimental method

The observational method is classified as:

- Descriptive methods
- Analytical methods

Analytical method again classified as:

a. Ecological or correlational study
b. Case-control study
c. Cohort study

Observational Method

In observational studies, the researcher observes and systematically collects information, but does not try to change the people (or animals, or reagents) being observed. In an experiment, by contrast, the researcher intervenes to change something (e.g., gives some patients a drug) and then observes what happens. In an observational study there is no intervention. Here researchers observe the effect of a risk factor, diagnostic test or treatment without trying to influence what happens. Such studies are usually 'retrospective'—the

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data are based on events that have already happened. Most workplace health research falls into this category.

Examples of Observational Studies

- A survey of drinking habits among students;
- A researcher who joins a biker gang to study their lifestyle (note, as long as the researcher does not try to change their behavior, it is an observational study); taking blood samples to measure blood alcohol levels during to take the blood, but you are not trying to change the blood alcohol level: it is just a measurement (In all epidemiological studies, the disease should be investigated and defined properly. It is very difficult to experience in interpreting the data without clear experience of disease and exposure).

Descriptive Methods

It is the first phase of epidemiological investigation. Descriptive epidemiology deals with the distribution of health-related states and events by time, place and person. The data is collected about the personal characteristics such as age, sex, marital status, occupation, education, income, dietary pattern, etc. Descriptive epidemiology provides a way of organizing and analyzing the data in order to understand variations in disease frequency geographically and over time, and how disease (or health) varies among people based on a host of personal characteristics (person, place, and time). This makes it possible to identify trends in health and disease and also provides a means of planning resources for populations.

It is the study of magnitude and distribution of disease or health status within a population by person, place and time.

- **Time distribution:** When is the disease occurring?
- **Place distribution:** Where is it occurring?
- **Person distribution:** Who is getting disease?

Purpose

- To provide a statistical overview of community health problems and gives clues about the etiological factors
- To provide information about diseases, i.e., incidence, prevalence and mortality rate, etc. by age, sex, occupation, social class
- For planning, organizing and implementation of health care services to deal with these problems.

Steps of Descriptive Epidemiology

- Defining the population to be studied
- Defining the disease under study
- Describing the disease by:
  - Time
  - Place
  - Person
- Measurement of disease
- Comparing with known indices
- Formulation of an etiological hypothesis.

- **Defining the population:** Descriptive studies are investigations of populations. It is based on population. The total number of population, age, sex, occupation, cultural characters and similar information needed for the study. The population needs to be large and stable.
- **Defining the disease under study:** The disease or condition being investigated must be defined. This is to obtain an accurate estimate of disease in a population. The disease will be defined operationally and it will different from their actual definition. For example, Defining TB means the patient should have sputum positive.
- **Describing the disease:** The primary objective of descriptive epidemiology deals with the distribution of health-related states and events by time, place and person.

Distribution by Time

The disease pattern 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 raised questions whether the disease is seasonal in occurrence, whether it shows periodic increase or decrease, whether it follows a consistent time trend. Disease rates change over time. Some of these changes occur regularly and can be predicted. For example, the seasonal increase of influenza cases with the onset of cold weather is a pattern that is familiar to everyone. By knowing when flu outbreaks will occur, health departments can time their flu shot campaigns effectively. Other disease rates make unpredictable changes. By examining events that precede a disease rate increase or decrease, we may identify causes and appropriate actions to control or prevent further occurrence of the disease.

- Short-term fluctuations or epidemic trends
- Periodic fluctuations or seasonal trends
- Long-term fluctuation or secular trends.

Short-term Fluctuation or Epidemic Trends

The epidemic is defined as 'the occurrence of disease in a community or any region of community. The cases or an illness or other health-related events clearly in excess than the normal expectancy'. The occurrence of disease can last for a short period of time. It can classified as:

I. **Common source epidemics:** When a common source is responsible for spreading any diseases rapidly we can consider as Common source epidemics. The disease can occurred by single source through single exposure or repeated exposure.
   a. *Single exposure or point source epidemics:* The exposure to the disease agent is brief and essentially simultaneous. All develop within one incubation period of disease, for example an epidemic of food poisoning. The epidemic tends to be explosive within a narrow interval of time. All the cases develop within one incubation period of disease. They can result from contamination of the environment (air, water, food, soil) by industrial chemicals or pollutants, for example, Bhopal Gas Tragedy in India.
   b. *Continuous or repeated exposure:* Sometimes the exposure form the same source may be prolonged. The people repeatedly exposing to same source repeatedly,

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a prostitute may be a common source in gonorrhea outbreak or the people who are using the same water from pond repeatedly suffered from water-borne diseases.

II. **Propagated epidemics:** A propagated epidemic is of infectious origin and results from person to person transmission of an infectious agent, i.e., epidemics of hepatitis A and polio. Propagated epidemics are more likely to occur where large numbers of susceptible are aggregated.
   a. Person to person
   b. Arthropod vector
   c. Animal reservoir

Periodic Fluctuations or Seasonal Trends

The occurrence of disease for a particular period of time.

Seasonal Trend

Seasonal variation is a well known characteristic of many communicable diseases like measles, varicella, and malaria, etc. Measles is usually at its height in early spring, gastrointestinal infections are prominent in summer month. By graphing the occurrence of a disease by week or month over the course of a year or more, we can show its seasonal pattern, if any. Some diseases are known to have characteristic seasonal distributions; for example, as mentioned earlier, the number of reported cases of influenza typically increases in winter. Seasonal patterns may suggest hypotheses about how the infection is transmitted, what behavioral factors increase risk, and other possible contributors to the disease or condition.

Long-term Fluctuation (Secular Trends)

Secular trends are continuous long-term changes in the frequency of diseases occurring over many years or decades. The secular trend describes the occurrence of disease over a prolonged period, usually years; it is influenced by the degree of immunity in the population and possibly nonspecific measures such as improved socioeconomic and nutritional levels among the population. For example, the secular trend of tetanus in the United States since 1920 shows a gradual and steady decline. The trends may be upward or downward, apparent or real. An apparent upward trend may be due to increased disease awareness improved diagnostic and treatment facilities, and improved recording and reporting of cases. A real downward secular trend may be caused by a favorable change in the epidemiological behavior of a disease. Among noncommunicable diseases, diabetes and heart diseases are upward secular trend. By graphing the occurrence of a disease by week or month over the course of a year or more, we can show its pattern, if any.

Distribution by Place

Studies of the geography of disease is one of the important dimensions of descriptive epidemiology factors that govern the distribution of diseases on this planet are extremely varied such as longitude, temperature, humidity, rainfall, soil, water, air, lifestyle, occupation, urbanization. Depending on their individual requirements, diseases show considerable variability in their geographic distribution. Distribution of diseases may be described as global, regional, national or local. It may examine mortality and morbidity in relation to socioeconomic factors, dietary differences and the differences in culture and behavior.

Global Distribution

Descriptive studies by place have shown that the pattern of disease is not the same everywhere. Global distribution of diseases reflects interesting pattern of endemicity. Malaria and leprosy which are tropical diseases requiring hot and humid climate, are prevalent in South East Asia, Africa and South and Central America. Filarial and hookworm diseases show specific distribution patterns.

National Distribution

National distribution relates to distribution within countries or national boundaries. In a vast country like India, a study of distribution of diseases is not without epidemiological curiosity. Inhabited by a huge population compressing of a variety of religious, cultural, linguistic and ethnic groups. India is an ethnic home to a host of tropical, subtropical and cosmopolitan diseases. For example, the distribution of endemic goiter, leprosy, malaria, nutritional deficiency diseases have all shown variations in their distribution in India. Some parts of country are more affected and some are less affected. The descriptive epidemiology provide data regarding the type of disease problems and their incidence, prevalence and mortality rates. These informations are needed to demarcate the affected areas and for providing appropriate health care service.

Regional Distribution

It is a comparative study of distribution of diseases within climatically homogenous regions of the world. It provides important clues of epidemiological interest. The data base of the six regional organizations of WHO facilitates such comparisons. The most leading types are oropharyngeal cancer in India, cervical cancer in Sri Lanka, breast cancer in Indonesia, and stomach cancer in Mongolia. Rural or urban variations in disease distribution are well known. Chronic bronchitis, accidents, lung cancer, cardiovascular disease, mental illness and drug dependence are usually more frequent in urban than rural areas. Skin and soil transmitted helminths may be more frequent in rural areas. The epidemiologist provides guidelines for disease prevention and control.

Local Distribution

Inner and outer city variations in disease frequency are well known. These 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. If there is clustering of cases in an area, it is an indication for further epidemiological enquiry.

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Distribution by Person

Diseases are not spread uniformly in human populations. The nature and frequency of diseases is also influenced by host characteristics such as age, sex, occupation, marriage, residence, sociocultural and socioeconomic background, stress migration.

Age

Age is strongly related to disease than any other single host factor. Certain diseases are more frequent in certain age groups like measles in childhood, cancer in middle age and atherosclerosis in old age. Age is associated with maturity of organ systems, efficiency of defense mechanisms and the state of health. Age also influences the attitude of individuals towards personal and community health.

Sex

Sex is a biological reality. It is an important personal attribute, responsible for dissimilar anatomical, physiological and psychological profiles of two gender groups. Disease like thyrotoxicosis, cholecysititis, diabetes, obesity, arthritis, psychoneuroses are more frequent in women while diseases like peptic ulcer, cancer lung, coronary heart disease and various kinds of accident more common in men. Female group shares a greater burden of morbidity associated with pregnancy and childbirth during the reproductive age period.

Occupation

Occupation may alter the habit pattern of employees, i.e., sleep, alcohol, smoking, drug addiction, etc. Distribution of diseases is also influenced by the principal occupation of people. While agriculture is main occupation the diseases like allergic reaction, worm infestation, are more frequent. In industrial towns, cities people suffer from diseases due to hazards of physical and chemical exposures, e.g., coal mines, silicosis sedentary occupation, heart diseases.

Marriage

Marriage is known to promote health and security of individuals. It influences their health habits and lifestyle. Disruption of marriage due to death, separation or divorce has adverse effect on health of spouses. The married people have lowest mortality, the widowed, separated and divorced have the highest mortality rates. Cancer cervix may be associated with multiple sexual contact.

Residence

Residence determines the nature of environment. The infection, infestations, deficiency and zoonotic diseases are common among rural folk, chronic bronchitis, cancer lung, coronary heart disease more frequent among city dwellers.

Sociocultural Milieu

Sociocultural milieu of individual determines their habits, customs, practices, beliefs which influence their health.

Economic Background

Poor class suffers from diseases of poverty associated with hostile environment, inadequate nutrition substandard housing, the rich class suffers from diseases of affluence associated with over nutrition, sedentary occupation and stressful environment.

Measurement of Disease

The disease can be measured by the tools of epidemiology, i.e., Rate ratio and proportions. Rate may be expressed in terms of mortality, morbidity, disability and so on. Descriptive epidemiology may use a cross sectional or longitudinal design to obtain estimates of magnitude of health and disease. Problems in human population. Morbidity has two aspects, i.e., incidence and prevalence. Incidence can be obtained from longitudinal studies and prevalence from cross sectional studies. Cross sectional studies based on a single examination of a cross section of population at one point in time. The results of the study are applied on the whole population. The cross section of the population is sampled carefully, so that it is representative of the whole population. It is also called as prevalence study. Cross sectional studies are useful for detailed community assessment, study of morbidity and underlying factors especially chronic diseases, for example study of diabetes or hypertension by personal characteristics and lifestyle. These studies are economical and comparatively quick to perform.

Comparing with Known Indices

Asking questions and making comparison are the two approaches of epidemiology. We can compare the epidemiological data with the data obtained other known indices like the global data, national data, etc. By making comparisons between different populations, it is possible to find out the disease etiology. By this we can define groups who are at risk.

Formulation of Hypothesis

As per the distribution of disease, utilizing the techniques of descriptive epidemiology, it is possible to formulate hypothesis relating to disease etiology. For example the smoking of 30–40 cigarettes per day causes lung cancer in 10% of smokers after 20 years of exposure.

Analytical Studies

In this second type of observational study, analysis is made to study the relationship between disease or other condition with different variables. There are various subtypes of analytical study.

Ecological or Correlational Study

Groups of population of different countries or geographical areas with different characteristics and values of variables are compared with reference to the frequency of occurrence of a disease associated with differing values of a variable may point towards association and possible cause and effect relationship.

Advantages

- Data collected for some other purpose is readily available for use

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- Can carried out without much cost or effort of data collection provide some indication
- It helps in initiation of depth studies
- It may be used to find out marked differences in frequencies of different disease.

Disadvantages

- Interpretation of results difficult as the data on other possible factors influencing occurrence may not be available
- Remain unsettled and the inference inconclusive
- Cause and effect relationship may be suspected but not proved
- Associations of levels of population may not be valid at individual levels.

Case-control Study

A case-control study is a type of study design used widely, originally developed in epidemiology. Although its use has also been advocated for the social sciences. It is a type of observational study in which two existing groups differing in outcome are identified and compared on the basis of some supposed causal attribute. Case-control studies are often used to identify factors that may contribute to a medical condition by comparing subjects who have that condition/disease (the 'cases') with patients who do not have the condition/disease but are otherwise similar the 'controls'. The case-control is a type of epidemiological observational study. An observational study is a study in which subjects are not randomized to the exposed or unexposed groups, rather the subjects are observed in order to determine both their exposure and their outcome status and the exposure status is thus not determined by the researcher.

This type of study known a case reference or retrospective study. It is often used to investigate cause of a disease, if the disease occurs rather infrequently. It starts with cases, i.e., persons who are not suffering from the disease, but would have been included in the study, if they were suffering, are investigated. In case-control study:

- The frequency of occurrence of the possible cause is compared in two groups of persons
- Differences in these two groups suggest association and causation
- These are longitudinal as compared to cross sectional.
- Called retrospective because the investigation goes back into the past of those persons who have developed the disease and compares with the past of the control
- Can be organized in a short time are economical and give results quickly
- They are inexpensive because the starting point is persons who have developed the disease
- Only a small number of person are required.

The case-control approach has emerged as a permanent method of epidemiological investigation case-control method has three distinct features.

1. Both exposure and outcome (disease) have occurred before the start of the study
2. The study proceeds backwards from effect to cause
3. It uses a control or comparison group to support of refute an inference.

Case-control study involves two populations' cases and control. The unit is the individual rather than the group, which focus on a disease or some other health problem that has already developed. Cases and controls must be comparable with respect to known 'confounding factors' such as age, sex, occupation, social status. For example, one can use as 'cases' the immunized children and look for factors of interest in their past histories. Case-control studies have been used for studies of many concerns and other serious conditions such cirrhosis of the liver, lupus erythematosis and congestive cardiac failure.

Steps of Case-control Study

There are four basic steps in conducting a case-control study which are as follows:

1. Selection of cases and controls
2. Matching
3. Measurement of exposure
4. Analysis and interpretation.

Selection of Cases and Controls

Identification of cases is easy, selection of suitable controls may present difficulties.

Selection of cases: A 'case' is crucial to the case-control study. It involves two specification such as (1) Diagnostic criteria and (2) Eligibility criteria.

Diagnostic criteria: The diagnostic criteria of the disease is based on the stage of disease or some characteristics or sign and symptoms of the disease. The criteria to be included in the study must be specified before the study is undertaken. Once the diagnostic criteria are established, they should not be altered or changed till the study is over.

Eligibility criteria: This is second criterion of eligibility. A criterion customarily employed is the requirement that only newly diagnosed cases within a specified period of time are eligible than old cases or cases in advanced stages of the disease.

Sources of cases: May drawn from hospitals or general population.

Hospitals: To select cases from hospitals, cases may be drawn from a single hospital or a network of hospitals admitted during a specified period of time.

General population: In a population based case-control study disease occurring within a defined geographic area during a specified period of time. The entire case series or a random sample of it is selected for study.

Control Group Selection

The controls must be free from the disease under study. They must be similar to the cases as possible, except for the absence of the disease under study. But need not be in good health; inclusion of sick people is sometimes appropriate, as the control group should represent those at risk of becoming

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a case. Controls should come from the same population as the cases, and their selection should be independent of the exposures of interest.

Controls can carry the same disease as the experimental group, but of another grade/severity, therefore being different from the outcome of interest. However, because the difference between the cases and the controls will be smaller, this results in a lower power to detect an exposure effect.

As with any epidemiological study, greater numbers in the study will increase the power of the study. Numbers of cases and controls do not have to be equal. In many situations, it is much easier to recruit controls than to find cases. Increasing the number of controls above the number of cases, up to a ratio of about 4 to 1, may be a cost-effective way to improve the study.

Difficulties may arise in the selection of controls if the disease under investigation occurs in sub-clinical forms, whose diagnosis is difficult. Selection of an appropriate control group is therefore an important prerequisite, we make comparisons draw inferences and make judgments.

Sources of controls includes:

- **Hospital controls:** The controls may be selected from the same hospital but with different illnesses other than the study disease. For example, if we are going to study cancer cervix patients, the control group may comprise patients with cancer breast, cancer of the digestive tract or patient with non-cancerous lesion and other patients. Many hospital patients may have diseases which are also influenced by the factor under study. For example, if one was studying the relationship of smoking and myocardial infarction and chooses bladder cancer cases as controls, the relationship between smoking and myocardial infarction may not have been demonstrated.
- **Relatives:** Controls may taken up from relatives. Siblings controls are unsuitable where genetic conditions are under study
- **Neighborhood controls:** The controls may be drawn from persons living in the same locality as cases, persons working in the same factory or children attending the same school
- **General population:** Population controls can be obtained from defined geographic areas by taking random sample of individuals free of the study disease.

Matching

Controls may differ from the cases in a number of factors such as age, sex, occupation, social status. Matching defined as the process by which we select controls in such a way that they are similar to cases with regard to certain pertinent selected variables which are known to influence the outcome of the disease. A confounding factor defined as one which is associated both with exposure and disease and is distributed unequally in study and control groups. A confounding factor is one that although associated with exposure under investigation, independently of any such association, a risk factor for the disease.

The study of the role of alcohol in the etiology of esophageal cancer, smoking is a confounding factor because:

- It is associated with the consumption of alcohol.
- It is an independent risk factor for esophageal cancer.

The effects of alcohol consumption can be determined only if the influence of smoking is neutralized by matching.

Age could be a confounding variable. We are investigating the relationship between steroid contraceptive and breast cancer.

If the women taking these contraceptives were younger than those in the comparison group, they would necessarily be at lower risk of breast cancer since this disease becomes increasingly common with increasing age. Matching protects against on unexpected strong association between the matching factor the disease is breast cancer.

Measurement of Exposure

Are important as those used to define cases and controls? Information about exposure should be obtained in the same manner both for cases and controls. This may be obtained by interviews, by questionnaires or by studying past records of cases such as hospital records, employment records.

Analysis

The final step is analysis to find out:

- Exposure rates among cases and controls to suspected factor.
- Estimation of disease risk associated with exposure.

Exposure rates: The exposure rates can be calculated among cases and controls. Example can be taken in a case study to identify the factors associated with tuberculosis.

Exposure	*Cases (with TB)*	*Control (without TB)*
Living in slum dwelling (overcrowded area)	30 (a)	70 (b)
Not overcrowded rural area	5 (c)	95 (d)
Total	(a + c)	(b + d)

$$\text{Exposure rate among cases} = \frac{a}{(a+c)} \times 100 = \frac{30}{35} \times 100 = 86\%$$

$$\text{Exposure rate among control} = \frac{b}{(b+d)} \times 100 = \frac{70}{165} \times 100 = 42\%$$

From the above analysis, it has been observed that the frequency of TB is higher among slum dweller.

Relative risk:

$$\text{Incidences among exposed} = \frac{a}{a+b}$$

$$\text{Incidences among nonexposed} = \frac{c}{c+d}$$

A typical case-control study does not provide a direct estimation of the incidence rate because there is no appropriate denominator or population at risk.

Odd ratio: From a case-control study odd ratio can be derived which is the measure of the strength of the association between risk factors and outcome.

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Formula for odd ratio is:

$$\frac{ad}{bc} = \frac{2850}{350} = 8.14$$

In the above example the slum dwellers are 8.1 risk of TB then normal rural population.

Estimation of risk: Estimation of disease risk associated with exposure is obtained by an index known as relative risk or risk ratio which is defined as the ratio between the incidence of disease among exposed persons and incidence among nonexposed.

Advantages of Case-control Study

- Relatively easy to carry out
- Rapid and inexpensive
- Require comparatively few subjects
- Particularly suitable to investigate rare diseases or diseases about which little is known. A disease which is rare in the general population such as leukemia in adolescents may not be rare in the general population.
- No risk to subjects
- Allow the study of several different etiological factor such as smoking, physical activity and personality characteristics in myocardial infarction
- Risk factors can be identified. Rational prevention and control programs can be established
- No attrition problems because case-control studies do not require follow up of individuals into the future
- Ethical problems minimal.

Disadvantages

- Problems of bias e.g., relies on memory or past records, the accuracy of which may be uncertain, validation of information obtained is difficult or sometimes impossible
- Selection of an appropriate control group may be difficult
- We cannot measure incidence and can only estimate the relative risk
- Do not distinguish between causes and associated factors
- Not suited to the evaluation of therapy or prophylaxis of disease
- Another major concern is the representatives of cases and controls, e.g., oral contraceptives and thromboembolic disease who had been admitted to hospitals with venous thrombosis or pulmonary embolism without medical cause and compared the history with that obtained from other women who had been admitted to the same hospital with other diseases who were matched for age, marital status and parity.

Cohort Study

A cohort is a group of people who share a common characteristic or experience within a defined period (e.g., A group of individuals are born, are exposed to a drug or vaccine or pollutant, or undergo a certain medical procedure or a group of people who were born on a day or in a particular period, say 1948, form a birth cohort. Hence, it is clear that the group of individuals sharing some common characteristic is kept under observation prospectively is called cohort study. The cohort must consist of individuals who are not affected by the disease or condition under study. Some of the individuals will have the characteristics which is suspected to be associated with that disease or condition while some individuals will be free of that conditions. Cohort of the individual is then observed and followed up to detect the occurrence of the disease under study. The size depend upon the frequency with which the disease occur. If the disease occur in frequent, a very large sized cohort will have to be kept under observation. For research purposes, a cohort is any group of people who are linked in some way and followed over time. Researchers observe what happens to one group that has been exposed to a particular variable—for example, the effect of company downsizing on the health of office workers. This group is then compared to a similar group that has not been exposed to the variable.

The difference in the incidence rates of the specific disease among those who have or do not have a particular characteristic provides evidence of association. Cohort study is known by a variety of names such as:

- Prospective study
- Longitudinal study
- Incidence study
- Forward looking study

Features of Cohort Studies

- Cohorts are identified prior to the appearance of the disease under investigation
- The study groups so defined are observed over a period of time to determine the frequency of disease among them
- The study proceeds forward from cause to effect.

Types of Cohort Studies

Three types of cohort studies have been observed on the basis of the time of occurrence of disease.

1. Prospective cohort studies
2. Retrospective cohort studies
3. A combination of retrospective and prospective cohort studies.

Prospective Cohort Studies

A prospective cohort study is one in which the outcome has not yet occurred at the time of investigation, e.g., long-term effects of exposure to uranium was evaluated by identifying a group of uranium miner and a comparison group of individuals not exposed to uranium mining and by assessing subsequent deviation of lung cancer in both the groups. The advantage of prospective cohort study data is that it can help determine risk factors for contracting a new disease because it is a longitudinal observation of the individual through time, and the collection of data at regular intervals, so recall error is reduced. However, cohort studies are expensive to conduct, are sensitive to attrition and take a long follow-up time to generate useful data. Nevertheless, the results that are obtained from long-term cohort studies are of substantially superior quality to those obtained from

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retrospective/cross-sectional studies. Prospective cohort studies are considered to yield the most reliable results in observational epidemiology. They enable a wide range of exposure-disease associations to be studied.

Retrospective Cohort Studies

A retrospective cohort study, also called a historic cohort study, generally means to take a look back at events that already have taken place. For example, the term is used in medicine, describing a look back at a patient's medical history or lifestyle. This type of study is known by a variety of names. Retrospective cohort study, historical cohort study, prospective study in retrospect and nonconcurrent prospective study. Retrospective cohort studies are generally more economical and produce results more quickly than prospective cohort study. In a historical cohort study the data concerning exposure and occurrence of a disease, births, a political attitude or any other categorical variable are collected after the events have taken place, and the subjects (those exposed and unexposed to the agent under study) are assembled from existing records or health care registers. A 'prospective cohort' defines the groups before the study is done, while historical studies, which are sometimes referred to as 'retrospective cohort', defines the grouping after the data is collected. It is a medical research study in which the medical records of groups of individuals who are alike in many ways but differ by a certain characteristic (for example, female nurses who smoke and those who do not smoke) are compared for a particular outcome (such as lung cancer). In retrospective cohort studies, a risk ratio or odds ratio gives an assessment of relative risk.

In the case of a retrospective cohort study, the investigator collects data from past records and does not follow patients up as is the case with a prospective study. However, the starting point of this study is the same as for all cohort studies. The first objective is still to establish two groups—exposed versus non-exposed; and these groups are followed up in the ensuing time period.

In a nutshell, in Retrospective Cohort Study, all the events—exposure, latent period, and subsequent outcome (e.g., development of disease) have already occurred in the past. We merely collect the data now, and establish the risk of developing a disease if exposed to a particular risk factor. On the other hand, Prospective Cohort Study is conducted by starting with two groups at the current point, and following up in future for occurrence of disease, if any.

Combination of Retrospective and Prospective Cohort Studies

Cohort is identified from past records and is assessed of date for the outcome. The somewhat is followed up prospectively into future for further assessment of outcome. The investigator collects data from past records and follow patients up as is the case with a prospective study. The starting point of this study is the same as for all cohort studies. The first objective is still to establish two groups—exposed versus nonexposed; and the back history of the two groups elements of prospective and retrospective cohort are combined.

- The Cohort is identified from past records and assesses of date for the outcome. The same cohort is the followed up prospectively into future for the further assessment of outcome example of Ambidirectional cohort study
- Curt-Brown and Dolls study on effects of radiation began in 1955 with 13,352 patients who received large dose of radiation therapy for ankylosing spondylitis between 1934 to 1954
- Outcome evaluated was death from Leukemia or aplastic anemia between 1934 to 1954
- A prospective component was added up in 1955 and surviving subjects were followed up to identify deaths in subsequent years.

Elements of a Cohort Study

- Selection of study subjects
- Obtaining data on exposure
- Selection of comparison groups
- Follow-up
- Analysis

Selection of Study Subjects

Study subjects are usually assembled in one of two ways:

1. General population
2. Select groups of the population. **For example,** persons with different degrees of exposure to the suspected casual factor.

General Population

When the exposure or cause of death is fairly frequent in population, cohorts may be assembled from the general population residing in well defined geographical, political and administrative areas. The exposed and unexposed segments of the population to be studied should be representative of the corresponding segments of the general population.

Select Groups

These may be special groups or exposure groups:

- **Special groups:** These may be professional groups, e.g., doctors, nurses, lawyers, teachers, civil servants, insured persons, obstetric population, college alumni, government employees, volunteers, etc.
- **Exposure groups:** If the exposure is rare, a more economical procedure is to select a cohort of persons known to have experienced the exposure. Cohorts may be selected because of special exposure to physical, chemical and other disease agents.

Obtaining Data on Exposure

Cohort members through personal interviews, e.g., collect smoking histories, reviewing past records certain kinds of information, e.g., dose of radiation, kinds of surgery or details of medical treatment can be obtained only from medical records, medical examination or special tests like blood

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pressure, serum cholesterol, ECG and by environmental surveys which is the best source for obtaining information on exposure levels of the suspected factor in the environment where the cohort lived or worked.

Selection of Comparison Groups

- **Internal comparisons:** Internal comparisons means the selection of comparison can be obtained from the same exposure group but the level exposure will be vary. In a single cohort study, the selection of its members may on the basis of information obtained according to the degrees or levels of exposure to risk before the development of the disease in question.
- **External comparisons:** When information on degree of exposure is not available it is necessary to put up an external control, to evaluate the experience of the exposed group with nonexposed group, e.g., smokers and nonsmokers. A cohort of radiologists compared with a cohort of ophthalmologists. The study and control cohorts should be similar in demographic data **(Table 3.1)**.

Comparison with General Population

If none is available, the mortality experience + of the exposed group is compared with the mortality experience of the general population in the same geographical area as the exposed people. For example, comparison of frequency of lung cancer among uranium mine workers with lung cancer in the general population where the miners resided or the comparison of frequency of cancer among asbestos workers with the rate in general population in the same geographic area.

Follow-up

At the start of the study, methods should be devised depending upon the outcome to be determined to obtain data for assessing the outcome. The procedures required:

- Periodic medical examination of each member of the cohort
- Reviewing physician and hospital records
- Routine surveillance of death records
- Mailed questionnaires, telephone calls, periodic home visits.

Analysis

Data are analyzed in terms of:

- Incidence rates of outcome among exposed and nonexposed
- Estimation of risk.

Table 3.1: Association of smoking with lung cancer.

Smoking	*Lung cancer*		*Total*
	Yes	No	
Yes	70	6930	7000
No	3	2997	3000
	73	9927	10000

Incidence Rates of Outcome

Incidence among exposed = a/a + b

Incidence among nonexposed = c/c + d

Relative Risk

$$RR = \frac{\text{Incidence of disease among exposed}}{\text{Incidence of disease among nonexposed}} = \frac{a/a+b}{c/c+d}$$

Attributable Risk

Attributable risk (AR) is the risk difference between exposed and unexposed groups. From above analysis it is clear that attribute risk is the [Risk (exposed) – Risk (unexposed)] = [A/(A+B)] – [C/(C+D)]. It is the quantity of disease that one could hope to avoid by removal of the risk factor in question. Thus, attributable risk is sometimes called the Risk Difference, or Excess Risk. The excess risk is "attributed" to the exposure. Attributable risk (AR) is often described as percentage

$$AR = \frac{\text{Incidence of disease among exposed} - \text{Incidence of disease among nonexposed} \times 100}{\text{Incidence of disease among exposed}}$$

$$AR = \frac{\frac{a}{a+b} - \frac{c}{c+d}}{\frac{a}{a+b}} \times 100$$

Find out RR and AR for above data

- Incidence of lung cancer among smokers
  70/7000 = 10 per 1000
- Incidence of lung cancer among nonsmokers
  3/3000 = 1 per thousand
  RR = 10/1 = 10
  (Lung cancer is 10 times more common among smokers than nonsmokers)

AR = 10 – 1/10 × 100 = 90%

(90% of the cases of lung cancer among smokers are attributed to their habit of smoking).

Among smokers – 70/7000 = 10/100

Among nonsmokers – 3/3000 = 1/1000

Advantages

- Incidence can be calculated
- Several possible outcomes related to exposure can be studied simultaneously, e.g., cohort studies designed to study the association between smoking and lung cancer showed association of smoking with coronary heart disease, peptic ulcer
- Cohort studies provide a direct estimate of relative risk
- Dose response ratios can also be calculated
- Comparison groups are formed before disease develops certain forms of bias can be minimized like misclassification of individuals into exposed and unexposed groups.

Disadvantages

- It involves a large number of people. They are unsuitable for investigating uncommon diseases or diseases with low incidence in the population

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Printed in India

Available at all medical bookstores
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JAYPEE BROTHERS
Medical Publishers (P) Ltd.
EMCA House, 23/23-B, Ansari Road,
Daryaganj, New Delhi - 110 002, INDIA
www.jaypeebrothers.com

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ISBN 978-93-5696-360-3